DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2016

THURSDAY, APRIL 23, 2015

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10 a.m., in room SD–124, Dirksen Senate Office Building, Hon. Roy Blunt, (chairman) presiding.

Present: Senators Blunt, Moran, Cochran, Alexander, Cassidy, Capito, Lankford, Murray, Durbin, Reed, Mikulski, Merkley, Schatz, and Baldwin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

STATEMENT OF HON. SYLVIA M. BURWELL, SECRETARY

OPENING STATEMENT OF SENATOR ROY BLUNT

Senator BLUNT. The Appropriations Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies will come to order. We are certainly pleased to have the Secretary with us today.

Secretary Burwell, thank you for taking your time to be here. One of my concerns that we have already talked about is finding out what spending number we actually have to work with and how we can work within the proposal that we have from the department, which is substantially higher than last year's level. I hope we can find common ground, so that we can really prioritize the concerns that we share with you and get the information, and understand where we need more information to figure out why we need to look at this a different way, when we need to look at this a different way.

The bill that the Congress has passed on the SGR I think gives you some ongoing capacity to look at how doctors deliver care in different ways, certainly the community health center element of that bill, the ability to fund the shortfall, and where the health centers would have been and where they have been for the last 5 years, was a significant part of that bill.

There are 23 million patients in 9,000 communities that are now served by those community health centers. The $150 per encounter cost is obviously a whole lot less than many of the alternatives,

particularly the emergency room as an alternative. And this committee and the Senate generally have been very supportive of the community health center concept, and we look forward to you continuing to work with us and us working with you to be sure we are fully taking advantage of that.

Last year, the Congress overwhelmingly passed reauthorization of the Child Care and Development Block Grant to improve health and safety standards and overall quality of childcare programs.

This is another area where the Congress has spoken. We look forward to working with you to see what we can do to meet the goals in that.

And finally, as we continue to work with the limited resources we are likely to have, funding should be targeting programs that have shown proven and effective results or programs that we all become convinced have that effective result potential out there. I am pleased that the department has requested a billion-dollar increase for NIH, the focal point of our Nation's medical research capacity.

One of the things that happened when I was in the House was a doubling of that funding, but then once we got to the doubling goal, that seemed to be the place to stop. I know that Dr. Collins and you and me and others don't want that same experience to repeat itself, that we set a worthy goal but don't understand the importance of having that goal extend beyond achieving the first marker in the goal. So we will continue to work with you and NIH on that as well.

I am pleased to be working on all these issues with Senator Murray. We are also lucky on this committee to have Senator Mikulski, the vice chairman of the committee, Senator Cochran the committee chairman often attends, as does Senator Alexander, the chairman of the authorizing committee. So a lot of people here very interested in what you are doing and appreciative of the work you have done in the time you have already been there.

So, Senator Murray.

STATEMENT OF SENATOR PATTY MURRAY

Senator MURRAY. Mr. Chairman, thank you very much. Good to be here with you again.

I am really pleased to welcome Secretary Burwell today to discuss the fiscal year 2016 budget request for the Department of Health and Human Services. I really want to thank you for all you do to improve health and well-being for our families and communities across the country.

There is really no question that when it comes to healthcare, we have taken historic steps forward in the last few years. As a result of the Affordable Care Act, more families are getting the quality, affordable coverage they need.

But the work didn't end with the law that was passed. Far from it. I am focusing on continuing to build on the progress made so far, to make sure we do keep moving forward with more coverage, not less, more affordability, not less, and more quality, not less.

Secretary Burwell, I know that continuing to make our healthcare system work better for families is a top priority for you as well. The role of your department is, of course, absolutely essen-

tial in this effort. The programs administered by the department impact families in a lot of important ways, from supporting biomedical research, to fighting public health threats, to expanding access to quality healthcare coverage for millions of workers and their families. Each of these investments and others is necessary if we want to improve our healthcare system and ensure that it puts patients first.

So I am disappointed that the budget resolution passed in the House and Senate really double down on the harmful sequestration cuts that are set to kick back in now.

Last Congress, as you know, I was very proud to work with Democrats and Republicans to break through the gridlock and dysfunction and reach an agreement that rolled back those harmful automatic sequestration cuts for 2 years, 2014 and 2015. And I really believe we have to build on that agreement now and lift the caps, so we can invest responsibly in areas that are so important to our country's health, education, jobs, and defense.

The President's budget, I was very pleased to see, does exactly that. It rolls back the unsustainable cuts to both defense and nondefense discretionary spending and is, therefore, able to support critical efforts to help our families and communities stay healthy.

The department's budget request for programs within this subcommittee's jurisdiction totals $76 billion. That is an increase of $4 billion, or 6 percent over last year. It proposes additional sensible investments in biomedical research, in public health, in programs that provide access to affordable healthcare as well as learning programs and affordable childcare for working programs.

I am looking forward to learning about many elements of the department's budget request in this hearing today. These include an increase of $1 billion for NIH, which would support a new precision medicine initiative and help maintain our country's leadership in biomedical innovation.

And there are other investments proposed in the department's budget that are also important to strengthening our economy now and over the long term.

I was really pleased that the budget includes a $1.5 billion increase for Head Start. That increase includes $1.1 billion to make sure every Head Start program serves children for a full school day and a full year, which will help make sure kids start kindergarten ready to learn.

I am also pleased to see the President's budget includes an increase of $370 million for the Child Care and Development Block Grant. This includes $266 million to implement the safety and quality improvements that were contained in last year's reauthorization, which the Senate approved last November with an overwhelming bipartisan vote of 88–1, due in no small part to the leadership of Vice Chairwoman Mikulski. We thank her for that.

Mr. Chairman, this bipartisan support shows that we all agree that quality childcare is essential to children's learning and their development, and it also helps parents to work, attend school, or pursue job training. So I hope we can all agree that that funding is needed to help working families to succeed.

The budget also requests $490 million in new funding for a department-wide initiative to address the growing problem of antibiotic resistance.

As you know, Virginia Mason Hospital in Seattle experienced a resistant outbreak earlier this year, which sickened over 30 people, possibly contributing to several deaths. These superbug outbreaks in hospitals are tragic and concerning.

Secretary Burwell, I applaud your proposal to address this very serious and increasing threat. I am also pleased that the President's budget maintains investments in helping families getting high-quality, affordable healthcare through the ACA, including $629 million to operate health insurance marketplace functions in over 30 States. This will allow Congress to continue working to improve quality, expand coverage, and drive down costs for our families.

The department's request also takes important steps forward in terms of helping seniors get the care that they need. Every year, over 4 million Americans, an average of 10,000 a day, turn 65. The growing Medicare population is straining CMS's operating budget, so I am glad the budget proposes additional resources to support that increasing workload.

Your budget also includes $875 million in funding for the Administration for Community Living nutrition services. That is a $60 million increase, which provides really vital support for older Americans nationwide, many of whom are low income.

I believe strongly that all families should be able to get the healthcare they need when and where they need it, which is why health centers and the National Health Service Corps are priorities of mine.

The agreement the President signed into law to fix the broken SGR system offered important support for health centers and the National Health Service Corps. And I'm glad the President's budget would help further expand access to these important resources for families across our country.

Now while I strongly support many of the priorities reflected in this budget, I do want you to know I am very concerned by the proposal to cut funding for breast and cervical cancer screenings for women. The Affordable Care Act expanded preventive services to millions of working women and has helped them save $483 million in out-of-pocket costs. But there are still today an estimated 4.5 million women who remain uninsured and are eligible for the cancer screening services that that program funds.

Mr. Chairman, I hope we can work together on a way to avoid cutting that extremely important program.

Our country has come a long way toward providing affordable, quality healthcare but there are many challenges ahead when it come to making our healthcare system work for families and put their needs first. Families have made it very clear that they don't want to go back to the bad old days when lobbyists and insurance companies, not patients, not the families themselves, had the power in our healthcare system.

Secretary Burwell, I know you share my hope that both parties can work together to build on the progress we have made so far and continue making improvements. That is certainly something I

hope we can do in this committee, and I look forward to working with you and all of my colleagues today and in the coming weeks and months.

With that, I will turn it back over to you, Mr. Chairman, and thank you.

Senator BLUNT. Thank you, Senator Murray.

Secretary Burwell, we are pleased you are here and look forward to your opening statement.

SUMMARY STATEMENT OF SYLVIA M. BURWELL

Secretary BURWELL. Thank you so much, Chairman Blunt, Ranking Member Murray, and members of the committee. Thank you all for having me up today to have an opportunity to talk about the HHS budget.

We saw the power of common ground in our recent bipartisan SGR repeal, and I applaud all of your efforts and hard work that got that passed.

The President's budget proposes to end sequestration, fully reversing it for domestic priorities in 2016, matched by equal dollar increases for defense funding. Without further congressional action, sequestration will return in full in 2016, bringing discretionary funding to its lowest level in a decade, adjusted for inflation.

We need a whole-of-government solution, and I hope that both parties can work together to achieve a balanced, common-sense agreement.

The budget before you makes critical investments in healthcare, science, innovation, and human services. It maintains our responsible stewardship of the taxpayers' dollars. It strengthens our work together with Congress to prepare our Nation for key challenges both at home and abroad.

For HHS, the budget proposes $83.8 billion in discretionary budget authority, $75.8 billion of which is for activities funded by this subcommittee. This $4.8 billion increase will allow our department to deliver impact today, as well as lay a strong foundation for tomorrow.

It is a fiscally responsible budget, which in tandem with accompanying legislative proposals would save taxpayers a net estimated $250 billion over the next decade. In addition, it's projected to continue slowing the growth in Medicare spending. It can secure $423 billion in savings as we build a better system that is smarter and a healthier delivery system.

In terms of providing all Americans with access to affordable, quality healthcare, it builds on our historic progress in reducing the number of uninsured and improving coverage for families who already had insurance. We saw a recent example of this progress with about 11.7 million Americans signing up or re-enrolling in health insurance through the marketplaces during this open enrollment.

The budget covers newly eligible adults in 28 States plus D.C., which expanded Medicaid, and it improves access to healthcare for Native Americans.

To support communities throughout the country, including underserved communities, it invests $4.2 billion in health centers and $14.2 billion to bolster our Nation's health workforce. It supports

more than 15,000 National Health Service Corps clinicians serving nearly 16 million patients in high-need areas, and it helps address health disparities.

To advance our common interest in building a better, smarter, healthier delivery system, it supports improvements to the way care is delivered, providers are paid, and information is distributed.

To advance our shared vision for leading the world in science and innovation, the budget increases funding for NIH by $1 billion to advance biomedical and behavioral research, among other priorities.

In addition, it invests $215 million in the Precision Medicine Initiative, a new cross-departmental effort focused on developing treatments, diagnostics, and prevention strategies tailored to the genetic characteristics of individual patients.

To further a common interest in providing Americans with the building blocks of success in every stage of life, this budget outlines an ambitious plan to make affordable, quality childcare available to every working- and middle-class family with young children. It supports evidence-based interventions to protect youth in foster care. And it invests to help older Americans live with dignity in their homes and communities, to protect them from identity theft.

To keep Americans healthy, the budget strengthens our public health infrastructure with $975 million for domestic and international preparedness, including critical funds to implement the global health security agenda and its core strategy of prevention, detection, and response.

It also invests in behavioral health services and substance abuse prevention. It includes more than $99 million in new funding to combat prescription opioid and heroin abuse, dependence, and overdose.

This is a top priority for our department, and I want to thank many members of this committee for your leadership in this area.

Finally, as we look to leave our department stronger, the budget invests in our shared priorities of cracking down on waste, fraud, and abuse, initiatives that are projected to yield almost $22 billion in gross savings from Medicare and Medicaid over the next decade. We are also addressing our Medicare appeals backlog with a coordinated approach.

I also want to assure you that I am personally committed to responding promptly and thoroughly to concerns and communication with and from Members of Congress, and close by taking a moment to say how proud I am of our HHS employees, from their work combating Ebola, to assisting the unaccompanied children at the border, to the commitment they show day in and day out, as they routinely go above and beyond the call of their work to help their fellow Americans obtain the building blocks of healthy and productive lives.

I look forward to working closely with all of you as we advance our common interests on behalf of the American people. Thank you, and with that, I look forward to your questions.

[The statement follows:]

PREPARED STATEMENT OF SYLVIA M. BURWELL

Chairman Blunt, Ranking Member Murray, and Members of the Committee, thank you for the opportunity to discuss the President's fiscal year 2016 Budget for the Department of Health and Human Services (HHS).

I want to begin by thanking members of this Subcommittee and your colleagues in the Senate and the House of Representatives for the bipartisan, bicameral efforts you have just undertaken in passing the Medicare Access and CHIP Reauthorization Act of 2015. As you know, this Act establishes a long-term policy solution to fix Medicare's flawed Sustainable Growth Rate (SGR) formula, replacing a broken system with one that offers predictability and advances value-based payments that reward quality and efficiency. The legislation also includes similar policies that were proposed in the President's Budget, such as requiring that Social Security numbers be removed from Medicare identification cards, increasing income-related premiums for Medicare beneficiaries, and reforming payments to post acute providers. These policies, along with other changes in the legislation, will help protect the integrity of Medicare and contribute to slowing healthcare cost growth.

I also want to express my gratitude for continued funding for the Children's Health Insurance Program, which provides comprehensive and affordable health coverage to millions of children. In addition, thank you for your continued support for critical safety net programs, including our Nation's health centers, the Home Visiting Program, the National Health Service Corps, and Teaching Health Centers Graduate Medical Education Program. These programs will ensure that millions of Americans will continue to have access to the healthcare and services they need to lead healthy and productive lives.

Five years ago, another major piece of legislation was enacted. And today, thanks to the Affordable Care Act (ACA), middle class families have more security, and since the passage of the ACA, about 16.4 million uninsured people have gained health insurance coverage.. In the private market, millions more now have access to expanded coverage for preventive healthcare services, such as a mammogram or flu shot, without cost sharing. At the same time, as a Nation we are spending our healthcare dollars more wisely and starting to receive higher quality care.

In part due to the ACA, households, businesses, and the Federal Government are now seeing substantial savings. Today, healthcare cost growth is at exceptionally low levels, and premiums for employer sponsored health insurance are about $1,800 lower per family on average than they would have been had trends over the decade that preceded the ACA continued. Across the board, the Department has continued its commitment to the responsible stewardship of taxpayer dollars through investments in critical management priorities. We have strengthened our ability to combat fraud and abuse and advance program integrity, further driving savings for the taxpayer while enhancing the efficiency and effectiveness of our programs.

The Department has done important work addressing historic challenges, including the coordinated whole-of-government responses to Ebola both here at home and abroad and to last year's increase in unaccompanied children crossing the Southwest border into Texas.

The President's fiscal year 2016 Budget for HHS builds on this progress through critical investments in healthcare, science and innovation, and human services. The Budget proposes $83.8 billion in discretionary budget authority, an increase of $4.8 billion from fiscal year 2015 appropriations. This additional funding will allow the Department to make the investments that are necessary to serve the millions of American people who count on our services every day, while laying the foundation for healthier communities and a stronger economy for the middle class in the years to come. The Budget also further strengthens the infrastructure needed to prevent, prepare for, and respond to future challenges effectively and expeditiously.

The Department's Budget request recognizes our continued commitment to balancing priorities within a constrained budget environment through legislative proposals that, taken together, would save the American people a net estimated $228.2 billion in HHS programs over 10 years. The Budget builds on savings and reforms in the ACA with additional measures to strengthen Medicare and Medicaid, and to continue the historic slow-down in healthcare cost growth. Medicare proposals in our Budget, for example, more closely align payments with the costs of providing care, encourage healthcare providers to deliver better care and better outcomes for their patients, improve access to care, and create incentives for beneficiaries to seek high value services.

Providing all Americans with Access to Quality, Affordable Health Care

The President's fiscal year 2016 Budget request builds on progress made to date by focusing on access, affordability, and qualit—goals that we share with Congress

and hope to work on together, in partnership, moving forward. The Budget also continues to make investments in Federal public health and safety net programs to help individuals without coverage get the medical services they need, while strengthening local economies.

Expanding Options for Consumers through the Health Insurance Marketplaces.—The ACA is making quality, affordable health coverage available to millions of Americans who would otherwise be uninsured. As of March more than 11 million consumers selected a plan or were automatically re-enrolled through the Health Insurance Marketplaces for coverage in 2015. At the same time, consumers are seeing more choice and competition. There are over 25 percent more issuers participating in the Marketplace in 2015 compared to 2014. Not only that, in 2015, nearly 8 in 10 Federal Marketplace customers can get coverage for $100 or less per month after applicable tax credits.

Partnering with States to Expand Medicaid for Low-Income Adults.—The ACA provides full Federal funding to cover newly eligible adults in States that expand Medicaid up to 133 percent of the Federal poverty level through 2016, and covers no less than 90 percent of costs thereafter. This increased Federal support has enabled 28 States and the District of Columbia to expand Medicaid coverage to more low-income adults many of whom are employed individuals. Just recently we saw another State, Indiana, join us to bring much needed access to healthcare coverage to a State-estimated 350,000 uninsured low-income residents. Across the country, as of January 2015, nearly 11.2 million additional individuals are now enrolled in Medicaid and CHIP compared to the summer of 2013. As Secretary, I am personally committed to working with Governors across all 50 States to expand Medicaid in ways that work for their States, while protecting the integrity of the program and those it serves.

Improving Access to Health Care for American Indians and Alaska Natives (AI/AN).—Reflecting the President's commitment to improving health outcomes across tribal nations, the Budget includes $6.4 billion for the Indian Health Service to strengthen programs that serve over 2.2 million American Indians and Alaska Natives at over 650 healthcare facilities across the United States. The request fully funds estimated Contract Support Costs in fiscal year 2016 and proposes to modify the program in fiscal year 2017 by reclassifying it as a mandatory appropriation, creating a longer-term solution.

Bolstering the Nation's Health Workforce.—The Budget includes a $14.2 billion investment in our Nation's healthcare workforce to improve access to healthcare services, particularly in rural and other underserved communities. That includes support for over 15,000 National Health Service Corps clinicians, who will serve the primary care, mental health, and dental needs of nearly 16 million patients in high-need areas across the country. Nearly half of all current Corps providers work in rural communities. The Budget also creates new funding for graduate medical education in primary care and other high-need specialties, which will support more than 13,000 residents over 10 years, and advance the Administration's goal of higher-value healthcare that reduces long-term costs.

To continue encouraging provider participation in Medicaid, the Budget invests $6.3 billion to extend the enhanced Medicaid reimbursement rate for primary care services, and makes strategic investments to encourage primary care by expanding eligibility to obstetricians, gynecologists, and non-physician practitioners. A January 2015 study by University of Pennsylvania and Urban Institute researchers found that the share of Medicaid enrollees who successfully got appointments with primary care providers grew by nearly 8 percentage points between 2012 and 2014, when the program was fully implemented.

Investing in Health Centers.—Health centers are essential sites where America's most vulnerable populations can access the healthcare they need. This is true for over 442,000 individuals in Missouri and over 836,000 individuals in Washington. Health centers are also key in reducing the use of costlier care through emergency departments and hospitals. The Budget includes $4.2 billion for health centers to serve approximately 28.6 million patients in fiscal year 2016, including an estimated 10.6 million rural Americans at more than 9,000 sites in medically underserved communities throughout the country. The Budget also provides the resources to open 75 new health center sites in areas of the country where they currently do not exist, including 30 projected new sites in rural areas.

Delivering Better Care and Spending our Health Care Dollars Wisely

If we find better ways to deliver care, pay providers, and distribute information, we can receive better healthcare and spend our dollars more wisely, all the while supporting healthier communities and a stronger economy. To build on and drive progress on these priorities, we are focused on the following three key areas:

Improving the Way Care is Delivered.—The Administration is focused on improving the coordination and integration of healthcare, engaging patients more fully in decisionmaking, and improving the health of patients—with an emphasis on prevention and wellness. HHS believes that incentivizing the provision of preventive and primary care services will improve the health and wellbeing of patients and slow cost growth over the long run through avoided hospitalizations and additional office visits. The Administration's efforts around patient safety and quality have made a difference—reducing hospital readmissions in Medicare by nearly eight percent, translating into an estimated 150,000 fewer readmissions between January 2012 and December 2013 and reducing hospital-acquired conditions by 17 percent from 2010 to 2013, saving an estimated 50,000 lives and decreasing healthcare spending by approximately $12 billion according to preliminary estimates.

Improving the Way Providers are Paid.—The Administration is testing and implementing new payment models that reward value, quality, and care coordination—rather than volume. HHS has seen promising results on cost savings with alternative payment models: already, existing Accountable Care Organizations (ACOs) programs have generated combined total program savings of $417 million to Medicare. To shift Medicare reimbursement from volume to value, and further drive progress in the healthcare system at large, the Department has announced its goal of making 30 percent of traditional, or fee-for-service, Medicare payments value providers through alternative payment models by 2016 and 50 percent by 2018.

Improving the Way Information is Distributed.—The Administration is working to create transparency of cost and quality information and to bring electronic health information to the point of care—enabling patients and providers to make the right decisions at the right time to improve health and care. The Centers for Medicare & Medicaid Services (CMS) is making strides to expand and improve its provider compare websites, which empower consumers with information to make more informed healthcare decisions, encourage providers to strive for higher levels of quality, and drive overall health system improvement. To improve communication and enhance care coordination for patients, the fiscal year 2016 Budget also includes a substantial investment ($92 million) in efforts supporting the adoption, interoperability, and meaningful use of electronic health records.

Leading the World in Science and Innovation

Investments in science and innovation have reshaped our understanding of health and disease, advanced life-saving vaccines and treatments, and helped millions of Americans live longer, healthier lives. With the support of Congress, there is more that we can do together. The President's fiscal year 2016 Budget request lays the foundation to maintain our Nation's global edge in medical research. This Budget for the National Institutes of Health (NIH) supports ongoing research and provides real investments in innovative science.

Advancing Precision Medicine.—The fiscal year 2016 Budget includes $215 million for the Precision Medicine Initiative, a new cross-Department effort focused on developing treatments, diagnostics, and prevention strategies tailored to the genetic characteristics of individual patients. This effort includes $200 million for NIH to launch a national research cohort of a million or more Americans who volunteer to share their information, including genetic, clinical and other data to improve research, as well as to invest in expanding current cancer genomics research, and initiating new studies on how a tumor's DNA can inform prognosis and treatment choices. The Department will work to modernize the regulatory framework to aid the development and use of molecular diagnostics, and develop technology and define standards to enable the exchange of data, while ensuring that appropriate privacy protections are in place. With the support of Congress, this funding would allow the Department to scale up the initial successes we have seen to date and bring us closer to curing the chronic and terminal diseases that impact millions of Americans across the country.

Supporting Biomedical Research.—The fiscal year 2016 Budget includes $31.3 billion for NIH, an increase of $1 billion over fiscal year 2015, to advance basic biomedical and behavioral research, harness data and technology for real-world health outcomes, and prepare a diverse and talented biomedical research workforce. This research is critical to maintaining our country's leadership in the innovation economy, and can result in life-changing breakthroughs for patients and communities. For example, that NIH estimates it will be able to spend $638 million under this Budget request on Alzheimer's research, an increase of $51 million over fiscal year 2015, which will position us to drive progress on recent advances in our understanding of the genetics and biology of the disease, including drugs currently in clinical trials, and those still in the pipeline.

Ensuring the Building Blocks for Success at Every Stage of Life

As part of the President's plan to bolster and expand the middle class, the Budget includes a number of proposals that help working Americans meet the needs of their families—including young children and aging parents.

Investing in Early Learning.—High-quality early learning opportunities both promote children's healthy development and support parents who are balancing work and family obligations. Across the United States, many American families face real difficulties finding and affording quality child care and early education. In 2013, parents on average paid more than $10,000 per year for full-time care for an infant at a child care center—higher than the average cost of a year's in-State tuition and fees at a public 4-year college. The Budget outlines an ambitious plan to make affordable, quality child care available to every low-income and middle-class family with young children; to expand access to high-quality early learning opportunities through the Head Start and Early Head Start programs; and to invest in voluntary, evidence-based home visiting programs that have been shown to leave long-lasting, positive impacts on parenting skills, children's development, and school readiness. These investments complement proposals at the Department of Education to provide high-quality preschool to all 4 year olds from low-and moderate-income families and expand programs for middle-class children as well.

The President's child care proposal builds on the reforms passed by Congress in the bipartisan reauthorization of the Child Care and Development Block Grant enacted last fall. The proposal makes a landmark investment of an additional $82 billion over 10 years in the Child Care and Development Fund (CCDF), which by 2025 would expand access to more than 1 million additional children under age four, reaching a total of more than 2.6 million children overall in the program. At the same time, the proposal provides resources to help States raise the bar on quality, and design programs that better serve families facing unique challenges in finding quality care, such as those in rural areas or working non-traditional hours.

The Budget includes an additional $1.5 billion above fiscal year 2015 to improve the quality of Head Start services and expand access to Early Head Start, including through Early Head Start—Child Care Partnerships. The proposal will ensure that all Head Start programs provide services for a full school-day and a full-school-year and increase the number of infants and toddlers served in high-quality early learning programs. It will also ensure that program funding keeps pace with inflation and that the program can restore enrollment back to the 2014 level.

Research by the President's Council of Economic Advisors indicates that investments in high-quality early education generate economic returns of over $8 for every $1 spent. Not only that, studies show high-quality early learning programs result in better outcomes for children across the board—with children more likely to do well in school, find good jobs and greater earnings, and have fewer interactions with the criminal justice system. These programs also strengthen parents' abilities to go to work, advance their career, and increase their earnings. That is why the Administration has outlined a series of measures, including tax cuts for working families, to advance our focus on improving quality, while also dramatically expanding access.

Supporting Older Adults.—The number of older Americans age 65 and older with severe disabilities—defined as 3 or more limitations in activities of daily living—that are at greatest risk of nursing home admission, is projected to increase by more than 20 percent by the year 2020. With 2015 marking the year of the White House Conference on Aging, the Department's Budget request includes $1.7 billion for Aging Services within the Administration for Community Living for investments that address the needs of older Americans, many of whom require some level of assistance to continue living independently or semi-independently within their communities. The Budget includes common-sense reforms that help to protect older Americans from identity theft, while supporting increased funding to support family caregivers and to expand home and community-based services and supports.

Improving Child Welfare.—The Department's Budget also proposes several improvements to child welfare programs that serve children who have been abused and neglected or are at risk of maltreatment. The Budget includes a proposal that has generated bipartisan interest that would provide $750 million over 5 years for an innovative collaboration between the Administration for Children and Families (ACF) and CMS that would assist States to provide evidence-based interventions to youth in the foster care system to reduce the over-prescription of psychotropic medications. There is an urgent need for action: ACF data show that 18 percent of the approximately 400,000 children in foster care were taking one or more psychotropic medications at the time they were surveyed. It also requests $587 million over 10 years in additional funding for prevention and post-permanency services for children in foster care, most of which must be evidence-based or evidence-informed. It in-

cludes savings of $69 million over 10 years to promote family-based foster care for children with behavioral and mental health needs, as an alternative to congregate care, and provides increased oversight of congregate care when such placements are determined to be necessary.

Keeping Americans Healthy

The President's fiscal year 2016 Budget strengthens our public health infrastructure, invests in behavioral health services, and prioritizes other critical health issues.

Investing in Domestic and International Public Health Preparedness.—The health of people overseas directly affects America's safety and prosperity, with far-reaching implications for economic security, trade, the stability of foreign governments, and the well-being of U.S. citizens abroad and at home. The Budget includes $975 million for domestic and international public health preparedness infrastructure, including an increase of $12 million for Global Health Security Agenda implementation to build the capacity for countries to detect and respond to potential disease outbreaks or public health emergencies and prevent the spread of disease across borders.

As new infectious diseases and public health threats emerge, HHS continues to invest in efforts to bolster the Nation's preparedness against chemical, biological, nuclear, and radiological threats. This includes a $391 million increase for Project BioShield to support procurements and replenishments of new and existing countermeasures and to advance final stage development of new products, and an increase of $37 million to replace expiring countermeasures and maintain current preparedness levels in the Strategic National Stockpile.

Combatting Antibiotic Resistant Bacteria.—The Centers for Disease Control and Prevention estimates that each year at least two million illnesses and 23,000 deaths are caused by antibiotic-resistant bacteria in the United States alone. The Budget nearly doubles the amount of Federal funding for combating and preventing antibiotic resistance within HHS to more than $990 million. The funding will improve antibiotic stewardship; strengthen antibiotic resistance risk assessment, surveillance, and reporting capabilities; and drive research innovation in the human health and agricultural sectors.

Addressing Prescription Drug and Opioid Misuse and Abuse.—The misuse and abuse of prescription drugs impacts the lives of millions of Americans across the country, and costs the American economy tens of billions of dollars in lost productivity and increased healthcare and criminal justice expenses. In 2009, total drug overdoses overtook every other cause of injury death in the United States, outnumbering fatalities from car crashes for the first time. In 2012 alone, 259 million opioid prescriptions were written—enough for every American adult to have a bottle. As part of a new, aggressive, multi-pronged initiative, the Budget includes more than $99 million in new funding this year in targeted efforts to reduce the prevalence and impact of opioid use disorders. The Budget also includes improvements in Medicare and Medicaid, including a proposal to require States to track high prescribers and utilizers of prescription drugs in Medicaid, which would save $710 million over 10 years and bolster other efforts to reduce abuse of prescription drugs.

Improving Access to Mental Health Services.—Mental and medical condition comorbidity results in decreased length and quality of life, and increased functional impairment and cost. Patients diagnosed with a serious mental illness die as much as 25 years earlier than other Americans, and they are also among the least likely to seek treatment. The Budget includes an increase of $35 million, a total of $151 million for the President's Now is the Time initiative to focus on prevention and treatment of mental health issues among students and young adults. Reaching 750,000 young people per year and training thousands of additional behavioral health professionals and paraprofessionals, this investment represents a substantial step toward reducing barriers for individuals seeking care. The additional funds will be used to increase workforce capacity across the Nation by expanding an existing partnership between SAMHSA and HRSA that addresses the number of licensed behavioral health professionals available and by creating a Peer Professionals program to provide training for individuals who have experienced their own behavioral health issues to help reach those in need of treatment. In addition, this increase will raise awareness about mental and substance use disorders and increase Americans' willingness to seek help through a social media campaign and other outreach efforts. The Budget also supports ongoing research at the National Institutes of Mental Health to prevent the first break of serious mental illness and change the trajectory of these disorders. Finally, the Budget proposes the elimination of Medicare's 190-day lifetime limit on inpatient psychiatric facility services, removing one of the last obstacles to behavioral health parity in the Medicare benefit.

Leaving the Department Stronger

The fiscal year 2016 Budget request positions the Department to most effectively fulfill our core mission by investing in a number of key management priorities that will strengthen our ability to combat fraud, waste, and abuse, strengthen program integrity, and enable ongoing cybersecurity efforts, among other areas.

Strengthening Program Integrity.—The fiscal year 2016 Budget continues to build on progress made by the Administration to eliminate excess payments and fraud. The Budget includes new investments in program integrity totaling $201 million in fiscal year 2016 and $4.6 billion over 10 years. This includes, for example, the continued funding of comprehensive efforts to combat healthcare fraud, waste, and abuse through prevention activities, improper payment reductions, provider education, audits and investigations, and enforcement. We thank this Committee for providing the full Health Care Fraud and Abuse Control (HCFAC) discretionary cap adjustment in the final fiscal year 2015 appropriation. The fiscal year 2016 Budget again requests the full discretionary cap adjustment be provided. This investment builds on important gains over the course of the past several years: from 2009 to 2014, programs supported by HCFAC have returned over $22.5 billion in healthcare fraud related payments. Together, the Department's proposed program integrity investments will yield $22 billion in gross savings for Medicare and Medicaid over 10 years.

Reforming the Medicare Appeals Process.—Between fiscal year 2009 and fiscal year 2014, the number of appeals received by the Office of Medicare Hearings and Appeals has increased by more than 1300 percent, which has led to a backlog that is projected to reach 1 million appeals by the end of fiscal year 2015. The Department has undertaken a three-pronged strategy to improve the Medicare Appeals process: (1) Take administrative actions to reduce the number of pending appeals and more efficiently handle new cases that are entering the appeals process; (2) Request new resources to invest at all levels of appeal to increase adjudication capacity and implement new strategies to alleviate the current backlog; and (3) Propose legislative reforms that provide additional funding and new authorities to address the appeals volume. The fiscal year 2016 Budget includes a comprehensive legislative package of seven proposals aimed both at helping HHS process a greater number of appeals and more efficiently handle new cases that are entering the appeals process, and requests additional resources for CMS, OMHA, and the Departmental Appeals Board to enhance their capacity to process appeals.

Protecting Unaccompanied Children.—HHS is responsible for ensuring that unaccompanied children who are apprehended by immigration authorities are provided shelter while their immigration cases are adjudicated. In the summer of 2014, the Administration responded to significant increase in the number of apprehended children with an aggressive coordinated Federal response focused on providing humanitarian care for the children as well as on stronger deterrence, enforcement, foreign cooperation, and border security. The number of unaccompanied children placed in ACF's custody thus far in fiscal year 2015 is below the fiscal year 2014 level for the comparable period, and HHS, DHS, and the other agencies with responsibilities for unaccompanied children expect arrival levels to remain stable. To ensure that ACF can care for all children referred from DHS in fiscal year 2016, and to promote the responsible stewardship of taxpayer dollars, the Budget includes level base funding from fiscal year 2015 of $948 million and creates a contingency fund that would only trigger additional resources if the fiscal year 2016 caseload exceeds levels that could be supported with existing program funds.

Improving Federal Spending Transparency.—A key Congressional priority is implementation of the Digital Accountability and Transparency Act of 2014 (DATA Act) which seeks to improve the transparency of Federal spending. HHS plays a critical, government-wide role in its implementation promoting transparency, facilitating better decisionmaking, and improving operational efficiency. The HHS Budget request includes $10 million to begin implementing new data standards, assessing impacts, facilitating long term policies, processes, and systems, and establishing the Section 5 grants pilot in coordination with OMB.

Conclusion

Members of the Committee, thank you for the opportunity to testify today. The President's fiscal year 2016 Budget request for HHS makes the investments critical for today while laying the foundation for a stronger economy for the middle class. I am looking forward to working closely with Congress and Members of this Committee on these priorities moving forward so that together we can best deliver impact for those we serve—the American people. I welcome any questions you may have.

Senator BLUNT. Thank you, Madam Secretary. We have votes scheduled at 11:45, so it will be my intention to be done when those votes occur. We will do 5-minute rounds, and we will go with Senator Murray and I, and the ranking member and the chairman of the full committee, and then we will alternate by order of arrival after that. And I should have time for a second round. And of course, there will be a week to submit questions in writing, if we don't get to those questions today.

EXCELLENCE IN MENTAL HEALTH

To start, I am going to ask a couple of questions about mental health and hope to get other questions in later, so that everybody has time to ask questions here.

First of all, we were able to get passed last year the Excellence in Mental Health Act, that Senator Stabenow and I cosponsored, in a way that allows States to be part of an eight-State pilot. I just want to thank you and your staff for working with us on those guidelines.

There was one late thing that still hadn't been decided that was decided yesterday, about what the boards of groups that apply need to look like. And hopefully we will have not only a number of States apply, but some sense that there are more States out there, and the country is ready to begin to treat these mental health issues like all other health issues.

I think that is a very important place for us to go, and hopefully we can do what we can in this committee to help us get there.

On the GAO report on mental health, as it relates to the department, could have been better. I believe just in the last few days, the department is going to move forward and look at those GAO recommendations. Of the 30 mental health programs out there, 13 are under SAMHSA. Four of those, apparently, there was no real plan to evaluate those, and that was one of the criticisms in the GAO report.

I'm just wondering, as you look at that report, as you look at SAMHSA, as you look at mental health generally as it relates to healthcare, one, your response to the GAO report, and two, is there anything else you want to say about the direction you hope to go with these mental health issues?

Secretary BURWELL. I think it is an important and critical time with the passage of the Affordable Care Act, the legislation that you passed, and mental health parity. I believe that, as a Nation, we are poised to take the biggest step we have taken in a very long time, to put these issues, behavioral health and mental health issues, on parity and to make progress on them. We look forward to doing that.

With regard to our conversations with you and Senator Stabenow, and thank you both for your leadership, we are going to try to beat the statutory deadlines that have been put in to implement your bill. The idea is that we can get that done and done quickly and get these things in place, so we have those eight States up and running, and continuing to do the work that it takes to implement mental health parity.

And that is about payment systems. That's about stigma. That's about how we implement our grant programs, which brings me to the GAO issue.

In the GAO report, I think there were two fundamental issues that we take very seriously. One has to do with the issue of coordination and making sure that we are coordinating across the government. I asked SAMHSA and the Assistant Secretary for Planning and Evaluation to come together to help do that inter- and intra-government coordination.

With regard to the question of our grant-making abilities and the question of that evaluation, I think you all know we have a new acting Deputy Secretary, Dr. Mary Wakefield, who is the highest ranking nurse in the Federal Government. And she comes from HRSA. So HRSA has made a lot of progress, with regard to this question of grants and evaluation. And we are going to see if we can share some of the best practices from our department and see how we can continue to make progress on this issue of evaluation.

Senator BLUNT. Thank you. And I think we want to look at what we can do to help enable you to do exactly that.

Secretary BURWELL. Thank you.

Senator BLUNT. If there are things that need to be said in report language or moved around in the budget, let's talk about that and be sure we get on that track where this happens.

I am going to go ahead and go to Senator Murray. A lot of questions that I might ask will be asked by others. We'll see what's left when we get back to me.

CONTRACEPTIVE COVERAGE

Senator MURRAY. Okay, thank you, Mr. Chairman.

Madam Secretary, for many women, the Affordable Care Act expanded coverage of all FDA-approved contraceptives has reduced their out-of-pocket costs and given them access to more effective methods of contraception. In fact, women have saved over $483 million because of that provision.

Unfortunately, there have been some ongoing reports of women across the country experiencing difficulties in securing guaranteed no-cost coverage from their plans. The Kaiser Family Foundation just released a report showing that there is still variation in how insurance carriers are adhering to the ACA requirement, and that not all methods may be covered without cost-sharing by women policyholders. As someone who cares very deeply about ensuring women have access to comprehensive healthcare, that is very concerning.

[The link to the report follows:]

http://kff.org/womens-health-policy/report/coverage-of-contraceptive-services-a-review-of-health-insurance-plans-in-five-states/

Senator MURRAY. Has HHS identified the carriers that are requiring cost-sharing or declining coverage or otherwise limiting coverage for some of these contraceptive methods?

Secretary BURWELL. The issue has been brought up broadly to us, and it is an issue we continue to work to make sure that our guidelines are very clear about the requirements of the ACA. We have seen some of these issues arise in certain pharmaceuticals

and drugs for HIV and other things. We are taking the steps to reinforce and be much clearer about our guidelines.

With regard to the specific cases, as they come in—the Kaiser report was a general report—it is about us understanding where those specific issues are. And where there are those specific issues, we will take them and follow up.

Senator MURRAY. And you plan to follow up on those?

Secretary BURWELL. We do plan to follow up, but it is a matter of the specifics being brought to us.

We understand the general problem, and it is one of the things I continue to have conversations to make sure people know, making sure that whether it is providing the transparency of information about what you do and do not cover, or making sure there are things like this issue of the coverage, that we are being clear about what the law is and our guidelines.

Senator MURRAY. Thank you very much. I really appreciate that.

ANTIBIOTIC RESISTANCE

I was really pleased to see that you are requesting $490 million to expand the multiagency effort to address antibiotic resistance. I talked about this in my opening remarks.

Outbreaks of these dangerous superbugs are occurring more frequently in hospitals around the country. I talked about Virginia Mason Medical Center in my home State. In February, I sent a letter to the Food and Drug Administration, urging them to take action to improve safety for patients and a follow-up letter in March calling for a review of FDA's practices surrounding the type of scopes that were involved at Virginia Mason and other places.

But we have to do more to prevent these infections from becoming resistant in the first place and to detect them as soon as possible. How would the additional resources that you have requested in your budget help with an outbreak at Virginia Mason or at any of these that we are seeing?

Secretary BURWELL. The Combating Antibiotic-Resistant Bacterial program, the CARB program, as we call it in our budget, has a number of elements in terms of what it is going to do.

We put out a strategy in 2014. And in 2015, we put out the action plan to go with that strategy. And our budget is the budget to support the action plan.

The elements are making sure that we are reducing the overuse, and that overuse is in both humans and animals. So my partner is Tom Vilsack at USDA, because the issue of antibiotics is an animal issue as well.

First, some of the funds will be used to support the reduction of that, in terms of both humans prescribing as well as in terms of animals.

Second, epidemiologically, we need to recognize quickly, as in the case of Virginia Mason. So CDC and others need the funding to make sure we have the epidemiologists to recognize when we have an outbreak, and we do it quickly.

The third thing we need to do is make sure that we are actually continuing to do the research to develop things that aren't resistant as we go forward.

Those are elements of the core strategy that the funds will go——

Senator MURRAY. So it is a multipronged approach?

Secretary BURWELL. It is a multipronged approach. And much of this sits with the Department of Health and Human Services, but we work across the other departments as appropriate and as necessary, with USDA being our primary partner, because of the animal connection.

Senator MURRAY. What about the issue of public health, like public health programs in Washington State? What role can they play?

Secretary BURWELL. That is a place where CDC is going to continue to work, and education is an important part of that. CDC is working with public health organizations as well as medical centers and training facilities to make sure people know about not overprescribing.

So as part of the public health and population health, CDC's ability to go in, make sure of the training and education and tracking is very important.

That's the other thing. We need better monitoring.

Senator MURRAY. I think this is really important, and we are going to see a growing number of cases similar to what we saw with other arenas, unless we take this head on.

So thank you for that.

Secretary BURWELL. It is millions already, so everyone has a sense—23,000 people died last year, but there are millions and millions of people who are contracting resistant disease. And much of that is occurring in hospitals, as you reflected with the situation at Virginia Mason.

Senator MURRAY. Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator.

Senator Cochran says he will speak in order of arrival, but I would want him to know, when it comes to allocate subcommittee amounts, that you can talk in this committee anytime you want to, no matter what they say anywhere else.

So on this side, I have Mr. Lankford, Mr. Alexander, Mr. Cassidy, Ms. Capito, and Senator Cochran. Over here, I have Senator Mikulski, Senator Reed, Senator Schatz, Senator Baldwin, and Senator Merkley.

Senator Lankford.

RECOVERY AUDIT CONTRACTORS

Senator LANKFORD. Thank you, Senator.

Madam Secretary, thank you for being here and thanks for the engagement on this. Let me just go through a couple of questions quickly.

There is a lot of conversation about the RAC audit process. That is not a new conversation to you at all. In your testimony, you even note that, starting in 2009, there is a 1,300 percent increase in Medicare and the auditing, and what is happening in the appeals process. There is obviously a problem that has happened.

So while you are accelerating the appeals process on this, I would like to get down to some of the root causes. There have been multiple changes to the RAC audit process. What is pending right now to continue to reform the RAC audit process in the days

ahead, beyond just the appeals process, which we can talk about separately, but the root cause of this?

Secretary BURWELL. With regard to the RAC process, I think it is important to step back. What RACs were put in place to do was to work on program integrity issues in terms of Medicare spending. This is something that Dr. Coburn and others helped us focus on, and this was put in place so that we could do the tracking. It has tracked many, and returned quite a bit of money to the Federal Treasury, in the billions of dollars.

There were negative unintended consequences that occurred. Congress has put a hold on certain parts of the RAC process.

Administratively, we have taken steps to change the RAC process.

Senator LANKFORD. So you all have made some changes. That is what I was trying to get at. What is next, of the changes that are pending still?

Secretary BURWELL. There are constraints that have been put on by the Congress in terms of our ability to go forward with RACs. That is something we want to do.

There is also contracting. We have had challenges to contracting.

So we need to get through those challenges and go through the regular process. We need to get the RACs back up and running, and we need to put in place and be able to implement the administrative changes, changes like, if it is not resolved within 90 days. We have these changes. We have done them administratively, but we are not being able to act on them fully as we like, because the process is not up and running. It is only on Part D.

The other thing is it actually does interact. So there are a number of changes. If the RAC case does not go forward and is not successful, there will be nothing paid. So we tried to fix some of the incentive issues that were causing problems.

It is related to the backlog issue, and the place where we believe we need some help from the Congress, and have had these conversations across a number of committees, are in that backlog process.

Senator LANKFORD. So the recovery audit data warehouse, putting that in place to make sure you don't have duplication of contracting and such is happening, and your contractors doing multiple claims. Last year, there was a statement that came out to say that is in the process, trying to reform that to make sure contractors actually—do you know if there has been any progress?

Secretary BURWELL. That is one I have to get back to you on.

[The information follows:]

The recovery audit data warehouse was built to make sure that a particular claim is not selected for review by two or more review contractors. However, the warehouse was not designed to keep a particular provider or issue from being selected for review by multiple review contractors. That will be one of the jobs of CMS's redesigned IT system, the Provider Compliance Reporting System.

The Provider Compliance Reporting System will combine data currently stored in the recovery audit data warehouse with several other data sources to provide CMS a single source of information about Medicare review programs from a provider perspective (e.g. when a provider received education on an issue, which claims were reviewed by the Medicare Administrative Contractor, Recovery Audit Contractor, or Supplemental Medical Review Contractor). Future plans include linking the Provider Compliance Reporting System to the Unified Case Management System. CMS

plans to use this new system, among other tools, to ensure that the same provider/issue is not being reviewed by different contractors at the same time.

Here is the timeline for getting Provider Compliance Reporting System up and running:

Completed Work

March 13: CMS posted a pre-solicitation
April 9: CMS/Office of Financial Management staff presented the Provider Compliance Reporting System to the CMS/Office of Informational Services Technical Review Board

Planned Work

June 2015: Issue a Request for Proposal to "8A" firms
Summer 2015: Accept and review bids
September 30, 2015: Award the contract

The statement of work requires bidders to build the Provider Compliance Reporting System on an existing CMS system that is connected to the CMS network (e.g. already has connectivity to all our contractors). Thus we can get it up and running faster than usual. I am hopeful that this module of the system will be operational by April 1, 2016.

Senator LANKFORD. Okay. That is one I know is pending. Dealing with good providers, obviously, they don't need to have this continuous RAC process coming through them, as frequent, or at least have smaller number pulled. Any kind of consequence for any contractor that is pulling a lot of files that are being overturned? So on both sides of this, there is an incentive for the contractors to also be good in the way they do it?

Secretary BURWELL. And the providers.

Senator LANKFORD. And the providers also.

Secretary BURWELL. The provider review is something that we have put in place in these administrative changes.

ICD–10

Senator LANKFORD. Okay. Let me ask about another issue not near as contentious as RAC audits. It has been very smooth in the process, the ICD–10 and the transition to that. Let's do something simple, as well.

This process transition, everyone is concerned about it, obviously. You all have dealt with it a long time in trying to work toward that transition. A lot of conversation about the advanced payments, what happens in the transition, how many small providers will be vulnerable during that time period?

It is the same issue with the RACs. The RACs can be managed by large providers. By small providers, it is very, very difficult for them to have large files that are pulled. The concern is out there as well for ICD–10. What happens in the transition there, the in-between?

The discussion has been out there on advanced payments. Is there a policy in place? Is there a process? Are there details coming out how it will be handled, or is that still being considered?

Secretary BURWELL. We now plan to go forward in October. I think you probably know there was a delay that was legislated. But right now, the plan is to go forward this October, in terms of moving to ICD–10.

Senator LANKFORD. Right.

Secretary BURWELL. As part of that process, we have been doing testing and communication with large players and small players. Most of the large players have been ready and are ready.

The question of any type of delay has to do with both cost, as well as the question of fairness and equity for those who are prepared to make the switch.

The hospital associations have done surveys, and we have very high percentages of people reporting that they are ready. For any of those who are not, we are still in the process, for anyone, we will provide the technical assistance. We will go in to try to do the training.

Senator LANKFORD. What about the advanced payments side of it? Is that still being discussed, to be able to help some of those individuals who are in the process?

The concern is there is not going to be a smooth transition from one to the other. Is it your confidence that there will be a very smooth transition? There is not going to be a gap for the small providers?

Secretary BURWELL. We are hearing, that they are ready, and that there is only a very small group that is not ready. But during the period from now until October, we want to continue to work with that group.

If you are hearing from those, it would be helpful to us——

Senator LANKFORD. I think it is just important for us to know you are confident there is not going to be a gap in payments that are going to further expose some of these smaller providers.

Secretary BURWELL. We are planning to make sure that we can go through and that people will be ready, so that there won't be those kinds of problems.

Senator LANKFORD. Okay.

Senator BLUNT. Senator Mikulski.

Senator MIKULSKI. Thank you very much, Mr. Chairman.

And of course, we welcome Secretary Burwell.

Before I go to my questions to her, Mr. Chairman, I would like to bring to your attention and the committee's attention that a very dedicated staff member of this committee for 13 years, who has worked for Senator Harkin, then worked for me, was also respected by Senator Specter, will be leaving. Adrienne Hallett who has worked for the committee for 13 years will be leaving to go to the executive branch. Actually, she is leaving to go to NIH, not for a clinical trial, but to again help Dr. Collins.

So I would like the committee, if we could, to give Adrienne a round of applause.

Secretary BURWELL. And I will say thank you. Thank you to the committee.

AFFORDABLE CARE ACT DESIGNATION

Senator MIKULSKI. Madam Secretary, of course, I'm glad to see you. So many of the great Federal assets of HHS are in Maryland, NIH, FDA, CMS, just to name the big three. And they have a tremendous impact on our economy, the jobs they provide and the jobs they stimulate.

We could not have the robust biotech community we have in Maryland without you. So we will of course be talking about those issues, but I am going to go right to a Maryland issue in a part of the State that is very familiar to you, my mountain counties up in Appalachia.

I have a situation where, due to the census, they are telling me that Allegany County, right next to our colleagues in West Virginia, you are a daughter of West Virginia, has lost their designation for Federal funding to qualify for the Affordable Care.

I wrote you a letter in February. Your staff has been calling back and forth, but we have been told recently there is nothing you can do.

Madam Secretary, I need you to look into this. You know Western Maryland. You know those mountain counties. You know they have lost population. You know that they have lost jobs. We don't want them to lose hope in their government.

The loss, the impact is $2 million. That might not be a lot by our spending up here, but that enabled them to attract doctors. It enabled them to harness volunteers, like Mercy, that reduced dental visits.

Could I have your assurance that you will actually look into this and not just have a lot of bureaucratic phone calls back and forth where they just say no?

Secretary BURWELL. Senator, I will look into it and see what the opportunities are for us to try and support this county.

Senator MIKULSKI. And not just a list of grants they can apply for. They are not an urban county.

CHILDCARE DEVELOPMENT BLOCK GRANT

So let me go on, though, to another issue, which really was a source of great exuberance among many of us, the fact that we worked together on a bipartisan basis to pass the Child Care Development Block Grant, working so closely with Senators Alexander and Burr, Senator Harkin and myself.

Could you tell us what now, because we passed an authorization, what you are doing to implement it, and particularly where we worked so hard on the quality provisions? Sure, we wanted more money. Sure, we wanted more slots. But we really focused on a bipartisan basis.

Could you tell us what is in the money to implement the law, and then enhance the quality and safety of our children?

Secretary BURWELL. Quality and safety are a large part of the implementation and what the money is for, and that is actually implementing the standards you all put in.

The second part of the money—and thank you all for your leadership on this—is are funds, because one of the other things we were asked to do is to make sure that childcare for unusual circumstances, for parents who work different hours, for places that are not receiving and hard to reach.

And this cuts across the entire suite as one looks at the continuum for children, home visiting, childcare in terms of implementing the authorization that you gave us. Also, in the budget is the childcare expansion that Senator Murray mentioned, the $82 billion over the 10-year period that would be for making sure that working families have access to childcare. And we don't want to forget Head Start and Early Head Start and those partnerships.

So this is a continuum. We work to implement that piece in the context of improving quality and safety across all of those pieces.

Senator MIKULSKI. But in a nutshell, it is a $370 million increase from last year. Is that correct?

Secretary BURWELL. That is correct.

Senator MIKULSKI. Of that $370 million, about $270 million is for the new quality provision.

Secretary BURWELL. That is correct.

Senator MIKULSKI. Do you feel that is adequate?

Secretary BURWELL. We do, to get us started. I think what we want to do is get the implementation started. And as we look at next year's budget, we will understand more.

Senator MIKULSKI. And then you also have $100 million for pilot programs for this gap in care.

Secretary BURWELL. That is right.

Senator MIKULSKI. I say to my colleagues, when we think of shift work, the days of factories are one thing, but, for example, we have nurses who are working the night shift.

I have the National Security Agency that works 24/7. Many are women who are cryptographers keeping America safe, often single mothers.

So I think we are on the right track. I also hope—my time is up—but that we could have additional conversation on the work that you are doing on both foster care and also on the unaccompanied children. Though the children seem to not be at the border the way they were, they are in our country and could continue to come. We cannot turn away from this very important issue.

So I look forward to dialogue with you, and with the chairman and the ranking member.

Secretary BURWELL. Thank you.

ELECTRONIC HEALTH RECORDS

Senator BLUNT. Senator Alexander.

Senator ALEXANDER. Thanks, Mr. Chairman.

Welcome, Madam Secretary. Senator Murray and I on the HELP Committee are trying to get a few things actually done. We have reported a bill on elementary and secondary education. We are moving ahead on higher education. As you know, we are going to get into innovation in medicine.

One other area where I believe we could get something done is electronic health records, and you and I have talked about that. You talked about the year and 9 months left for you, and what I would like to do is to move up toward the top of your list and our list doing something about electronic health records.

The government spent $28 billion subsidizing electronic health records. It sounded like a wonderful idea. But half the doctors have either tried and failed or are choosing not to participate in the program. Instead, they'll face Medicare penalties this year.

Doctors don't like their electronic medical record systems, by and large. They say they disrupt the workflow and interrupt the doctor-patient relationship, and they haven't been worth the effort.

An AMA commissioned study found electronic health records are the leading cause of physicians' dissatisfaction. A Medical Economics survey last year found nearly 70 percent of physicians say their electronic health records haven't been worth it.

Now I have met already with Andy Slavitt. At your suggestion, I am meeting with Dr. DeSalvo. And what I would like to do, with the committee here listening—well, one other thing. Senator Murray and I have formed a bipartisan working group on the HELP Committee to identify five or six problems in the electronic health records system that we could address administratively. In other words, you could do it, or legislatively, if we have to, we can do it.

So what I would like to ask you is will you commit to putting on your list of things you would like to get done in the year and 9 months that you plan to be here, working with us, identifying five or six things that would make this promise of electronic health records something that physicians and providers look forward to instead of something they endure?

Secretary BURWELL. Yes. After our meeting and our conversation, I think we got a working group of staff ready to go, and we are committed to do that.

I think this is extremely important in and of itself, but also because of all the things it touches. We are going to talk about so many things that touch this. I'm sure I'm going to get a question, hopefully, about opioids and heroin. Electronic records touch that issue. The precision medicine issues that we are talking about, electronic records touch that issue. Delivery system reform, creating a system of healthcare delivery that has better quality and is more effective and efficient, it touches that.

And so we should focus on it, in and of itself. Where healthcare is going and where everything is going in terms of our ability to serve the consumer, the patient, in the way we need to, this is a core part.

So I welcome the opportunity and look forward to putting the list together and look forward to getting it done. We will look at our administrative things, and we want to work with you all on what we need legislatively as well. There may be some things there.

Senator ALEXANDER. Great. There is a lot of interest on the committee. Senator Cassidy has expressed that. He is a physician himself. Other members on the Democratic side have expressed that.

OVERREGULATION

And one other area where I think we should work together, and we have talked about it, Senator Mikulski and I and Burr and Bennet asked some higher education folks to give us a report on the cost of overregulation. And they gave us 59 recommendations about what to do.

We are putting it together in legislation, and we are going to incorporate these ideas as much as we can in the Higher Education Act.

At the same time, the National Academy of Sciences has said that principal investigators of federally sponsored research projects spend 42 percent of their time on administrative tasks instead of research.

Now, we do a lot of talking here about needing more money for research. Taxpayers spend $30 billion a year on research and development at colleges and universities. NIH spends about $24 billion. Vanderbilt University hired the Boston Consulting Group to tell it how much it costs Vanderbilt to comply with Federal rules

and regulations, and the answer was $150 million for 1 year, and a lot of that had to do with research.

Now that is not all in your department, and it is not all in education, but my question is, will you work with us and help us work with other agencies to see if we can work with the national academies and take that 42 percent down, releasing hundreds of millions or maybe billions of dollars, which could be used for important research of the kind that all of us hope there should be more of.

Secretary BURWELL. Yes, I think it is an important issue. I think we can make progress. When I was at the Bill and Melinda Gates Foundation and we were doing grant-making, our grantees would always ask us to pay the administrative level that the Federal Government would.

So I believe we need to work on it. We need to work on it from our end in the Federal Government. But across, it will help even beyond the work that we do.

And I think for some of these things, we need to figure out where we are willing to take certain risks. Some of the administrative costs have to do with very important things, like tracking conferences and provisions that are put in. So I think this is a place that is ripe for us to have quality conversations about what are the things we can do to reduce some of that burden. And we want to make sure we are all clear what it means when we do the changes that we do.

So I welcome that chance, and I know our NIH colleagues, there are a number of things that are already on their list that they would like to talk about.

Senator ALEXANDER. Thank you, Madam Secretary.

Thanks, Mr. Chairman.

LIHEAP

Senator BLUNT. Senator Reed.

Senator REED. Thank you, Mr. Chairman.

And thank you, Madam Secretary, for your testimony and for your great leadership.

Let me focus on the topic of LIHEAP. Senator Collins and I have been, as you know, for years, committed to ensuring we have adequate resources. I am pleased to see your budget request is a slight increase from previous years, but still $200 million below the previous authorization and appropriation.

So what can we do to get LIHEAP further funded?

With weather patterns as they are, it is not just cold in the Northeast and families dealing with that. It is increasingly hot summers where air-conditioning is essential for people in the Southeast, Southwest, and the West Coast.

So can you help us?

Secretary BURWELL. In the budget proposal, what we did was propose the base level of LIHEAP at last year's level. We also proposed a contingency fund, and this actually gets to the issue of the variability, and what LIHEAP is about, and that we are having these huge changes.

What we were trying to do is create a fiscally responsible way to respond to the type of increasingly erratic weather that we are

seeing, and the contingency fund needs to be put in the budget, so that we have the contingency fund. But it would allow us to have some flexibility.

So funding at the base level, but then add a contingency fund that could help us. So that was our approach to working to get additional LIHEAP funding.

Senator REED. I commend you for, again, the increase. I think we have to do more. Senator Collins and I both—I will speak for her I think—look forward to work with you on this.

There is a related issue, and that is you have discretionary authority to move aside about 1 percent of appropriated funds and you consistently do that with LIHEAP. Today, there is about $34 million of LIHEAP funding that has not been spent. And there is, certainly, the need out there. Can you work to release those funds or commit them to make sure they are committed to LIHEAP?

Secretary BURWELL. I think at this point in time, we are doing the final review to understand if and when those funds will go. So we will work with you on that issue. We are 99 percent there with $3.3 billion spent. And the $34 million is the outstanding amount at this point.

SECTION 317 IMMUNIZATION PROGRAM

Senator REED. Thank you very much, Madam Secretary.

Let me turn quickly to another topic, and that is the CDC Section 317 immunization program. It buys the vaccine for many middle- and low-income families. It provides the structure for vaccination, which is to critical public health—in fact, I'm going to argue one of the most critical public health initiatives that we have taken in the history of public health.

It is somewhat disappointing that your budget is going to cut this program by $50 million next year, and particularly disconcerting because we are seeing the outbreak of some contagions we thought were—in my youth, like measles. And this Section 317 is also used to track that and respond to that.

So looking at all these issues, why are we cutting this program?

Secretary BURWELL. Like you, we agree and are very concerned about the vaccination issue, especially in the context of the measles outbreak that we have seen.

With regard to 317, there is also the additional complementary program. This is the children's vaccine fund. When you combine the two of those programs together, there is a net increase of $58 million in the budget overall.

With regard to 317, as we are implementing the Affordable Care Act, parts of 317 were used for those that were underinsured. And because when the ACA was passed, it was actually required that all plans do no cost-sharing.

So when I take my child in for the wellness visit, that vaccination doesn't have a co-pay.

Because of that reduction, the 317 money for vaccine purchase is being reduced because we have people who are now in a fully insured space.

With regard to the funding in 317 that does the kinds of things that are very important that you mentioned, that is something we

are doing more and more of through the CDC; none of those funds were cut as part of this.

Senator REED. You are doing analysis to ensure that there is no gap, that, in fact, children are getting the vaccines through the ACA mechanism?

Secretary BURWELL. The problem that Senator Murray raised with regard to contraception we have not seen with regard to vaccination, which is that people are in any way not covering that.

If that is something people are hearing about, please let us know. It is when we hear that we go back out with the guidance. We have not heard that from anyone at this point. That is the part that seems to be being implemented correctly. But if you are hearing something different, we want to know, because, obviously, this is an extremely important issue.

Yesterday, I did the formal swearing-in of the surgeon general. And as you all probably know, measles is one of the issues that he has been deeply focused on, including the public service announcement with Elmo. We are trying to do everything we can, work with the States directly, epidemiologically, educate, anything we can.

Senator REED. I think Elmo is a good point to cease questioning. Thank you.

Senator BLUNT. I agree.

Secretary BURWELL. My children now understand my job. When I took home the picture of me with Elmo, that they appreciated.

Senator BLUNT. That is the moment they knew you arrived.

Secretary BURWELL. Yes.

UNACCOMPANIED ALIEN CHILDREN

Senator BLUNT. Senator Cassidy.

Senator CASSIDY. Secretary Burwell, how are you?

Secretary BURWELL. Good morning, Doctor.

Senator CASSIDY. A couple of things. First, you had mentioned—this question has bugged me for a year. So when you mentioned the effort that CMS had made for those unaccompanied children coming to the board, when I was in the House last year, there was a roundtable, an oversight hearing.

Now as I recall, CMS had $800 million in the regular budget last year to care for the expected surge of unaccompanied children. And there was a physician there, and she had the Public Health Service uniform on. And I was a little critical because the response had been so poor. And she said, I am the first doctor, and I was just hired 2 weeks ago, and this is like July.

Now I don't expect you to have the answer as to how that $800 million now with you, but expect a question for the record. CMS or HHS had $800 million, and the first doctor was hired in the middle of the summer when they had requested a bump-up in anticipation of a surge of unaccompanied children.

So just to make that point, and I would like to follow up, and you can follow with that, because, again, I don't expect you to have that. But nonetheless, when you mentioned it, oh my gosh, it just popped up. It has bugged me ever since.

She was a dedicated physician, but she had been hired as the first physician. She said there were two or three nurses working on it, but never a physician, and only two or three nurses to handle

the whole program. No offense against the nurses. It was just so few of them.

ICD–10

Secondly, you had mentioned the ICD–10 effects. I am going to speak for that physician who is in a smaller practice. The big hospital chains are of course ready, but what I am reading here from athenahealth, but quoting CMS, CMS estimates that in the early stages of implementation, denial rates will rise by 100 percent to 200 percent, and days in accounts receivable will grow from 20 percent to 40 percent. It goes on to explain why.

So I will just say, according to your own Web site, that urologist in South Louisiana, who is in a one- or two-person practice, she cannot afford to have denials go from 100 percent to 200 percent and her AR growing by 20 percent to 40 percent.

Personally, I think the reasonable thing to do would be to delay the penalty phase for 2 years as people transition, because it is that doc who is just struggling to see however many patients she has a day and also comply with EHR, who suddenly is going to have her denials grow by 100 percent to 200 percent. Not because she's not doing it right, but because the system has changed.

Unless we are sympathetic, we are going to drive her out of practice. And that is what is happening.

AFFORDABLE CARE ACT

I also will put that plug in just as a kind of an esprit de corps for all those physicians who right now just feel—now this is something that perhaps you can address.

In February 2013, the CBO projected the per person cost of Medicaid for just that portion getting acute care, for example, the expansion population under the Affordable Care Act, would be $2,500 in 2014, only including estimates for the fully eligible.

Last month, the CBO projected an average per person cost of Medicaid for $3,460, including both partial eligible and fully eligible. Now this is a jump of $1,000 per beneficiary over the entire Nation, which is almost a 40 percent increase.

What is going on with Medicaid? We will disagree, but the Affordable Care Act is unaffordable for the taxpayer, if from year to year we have had a 40 percent jump in per person Medicaid costs.

Secretary BURWELL. So I will want to go look at exactly what that CBO references is, because across the Affordable Care Act in the system, Medicaid, as you probably know, is generally the least expensive option, in terms of service and care for individuals. So I am surprised by that CBO number, because as you and I had the chance to discuss in terms of the net and overall costs, we have seen that not happening.

So I apologize, I have not seen that particular number, and it is not indicative of what my understanding of what the cost curve is.

Senator CASSIDY. Sounds great.

Then one more thing let me just squeeze in, again, because you started off I think extolling the Affordable Care Act. I will point out that, apparently, only 2 percent of those with 400 percent or above income—i.e., not eligible for subsidies—only 2 percent of those eligible have signed up for insurance through the exchanges.

So the middle class is getting hosed by premiums, which have increased dramatically, and we are just going to leave the middle class behind when it comes to affordable health insurance.

Secretary BURWELL. So with regard to premiums in the employer-based market——

Senator CASSIDY. No, this is in the exchanges. Only 2 percent of those eligible for insurance through the exchanges have signed up for insurance.

Secretary BURWELL. I think with regard to the number that we have seen in terms of those eligible to receive insurance through the marketplace, as we have talked about, it is about 16.4 million people is the reduction, which is the largest reduction we have seen as a Nation in decades.

Senator CASSIDY. We can debate that, because, again, as we talked about, CBO reduced their baseline of those insured. And the numbers I have looked at, is that most of those newly insured have signed up through Medicaid, not through the exchanges.

Secretary BURWELL. CBO reduced their baseline of those uninsured.

Senator CASSIDY. Correct.

Secretary BURWELL. CBO recently reduced the estimated cost of the Affordable Care Act by approximately $300 billion.

Senator CASSIDY. Just for truth in advertising, that is because States didn't do the Medicaid expansion.

Secretary BURWELL. It was a combination.

Senator CASSIDY. And not as many people——

Secretary BURWELL. States didn't do the expansion, costs of healthcare cost increases were much smaller, and premiums were much lower than they had expected in their original. Fewer people moved from employer-based care to the marketplace than what was in CBO's original.

It was the combination of those three things that had the reduction. And CBO went from a number of about 55 million being uninsured—and that is total; that is not eligible for the marketplace—to 52 million. So what CBO did was actually reduce the number and, therefore, the percentage of uninsured that we now have, did.

So with regard to the question of number of people in the marketplace, we want that to continue to go up. We want to do everything we can. I think you saw we worked hard to have an open enrollment that served the consumer. It actually is important for us to have the conversation, so I welcome it.

Senator CASSIDY. Yes.

Secretary BURWELL. So we were trying to serve the consumer. And I think we saw and continue to see growth.

Can it be more? Can it be better? We would like to do that, and we would like to work on the ways that we can make more of those consumers come in and find that affordability.

Having traveled around the country and met the woman who said to me, you know how you treat MS? This is a working woman, three children. You get sick enough until you go to the emergency room, and they'll treat you. And she said, now I have a card, and now I'm going to learn how to treat MS.

Senator CASSIDY. We are 3 minutes over, but I will finish by the woman I spoke to who says I'm 56-years-old.

Senator BLUNT. We actually are 3 minutes over.

Senator CASSIDY. And I am paying $500 more a month for insurance, and I don't need what I'm getting with a $6,000 deductible.

TELEHEALTH

Senator BLUNT. Mr. Schatz.

Senator SCHATZ. Thank you, Mr. Chairman.

Thank you, Secretary Burwell.

I have a question about telehealth. I am a big believer in telehealth. I think the VA has done a lot of good work in this space. The DOD has done good work. Private healthcare providers are really expanding their services as a way to improve clinical outcomes. It's also a way to save money in systems.

And I just want to know what Medicare, in particular, is doing, what you think you can do additionally within the confines of 1834(m) and whatever kind of statutory restrictions you may have.

Could you just sort of divide the question into those two categories: where you think the law really needs to be changed and you're stuck, and what you think you could be doing within the confines of the statute that you are not doing yet.

Secretary BURWELL. I think the places where we can do more are in our innovation center. In the funding we receive for the innovation, and that was part of the Affordable Care Act, there we are seeing and doing a number of innovative projects including telehealth. So that is one place where we are acting.

Several of the things that we have funded that include telehealth components that we think are important. And I think you all know the statutory requirements with regard to it meeting success are very high, so it will take time and measurement to get there and prove that. But we want to work to do that, hit those measures, because that's when you can scale them.

We have to be able to show, quality and cost. So we have to get there and do that.

The other place, in terms of the authorities we currently have, have to do with some of the ACO work we are doing, Pioneer ACOs and others, accountable care organizations.

Actually, we just recently put out a sort of a version 2.0 and telemedicine was increased in that.

With regard to statutory issues, I think we need to have conversations about places we can talk about where there might be changes that would free us to do more telehealth. And that is on the Medicaid payment side.

Senator SCHATZ. Right. Okay, so let's do two things. First of all, let's work together, and I know Senator Wicker as the chairman of the subcommittee on telecommunications, had a really good bipartisan hearing on the potential for telehealth. I think there were 17 members of the subcommittee who attended. There was broad and deep enthusiasm on a bipartisan basis.

I want to work with him. I know a lot of other members are anxious to get going in that space. And I think he's going to work on legislation to introduce in this Congress in that space.

So first of all, we have to work on whatever changes in the law are necessary. I also would encourage you, because during that hearing, the national organization for telehealth, I think that is

what they are called, but in any case, the national organization that advocates in this space thinks that you can be doing more even within the constraints of 1834(m). So I know you did this next gen ACO, but some my staff and others are saying you could move a little quicker in store and forward, and some other areas.

So I am anxious. I know you believe in this. I know the administration believes in this. And I know there are other executive branch agencies that are moving faster.

Now some of that is because of the law itself. But some of it may not be. So if you could just check with your staff to see that we are doing absolutely everything that we can possibly be doing to advance the ball on this? You are one of the biggest payers around.

And so on the telecom subcommittee, a lot of the questions were logistical and clinical, and setting up markets and the rest of it. And in my view, a lot of those problems downstream get solved if the payer comes to the table. That all gets settled, because there will be a built-in market. I think you can make some additional incremental progress, as we work on legislation together.

Secretary BURWELL. That's great, because I think you know the payment has to do with, is it something that exists? Or does it have a certain proof point?

Those are the places where I think there is room to see if we can push our authorities. If you all have ideas, we welcome that.

Senator SCHATZ. Thank you very much.

HRSA BLACK LUNG CLINICS

Senator BLUNT. Senator Capito.

Senator CAPITO. Thank you, Mr. Chairman.

And if it's not lost on anybody on this committee to know that we are both daughters of West Virginia, and I'm very proud of the Secretary. She does a great job representing our State and our Nation.

Secretary BURWELL. Thank you.

Senator CAPITO. So it is an honor for me to be here with you for the first hearing.

The question I had specifically, and I mentioned this the other day when we were talking, is about the Black Lung clinics. HRSA made a change in their allocation to cap it at $900,000, which actually costs West Virginia some Federal dollars, trying to make sure that we meet the challenge of ridding ourselves and treating Black Lung disease, which, unfortunately, we have.

What is the rationale for this per grantee cap? Is this going to continue? We were able to sort of recover a little bit through another grant process, but I am concerned about this because of the deep need that we have in our home State.

Secretary BURWELL. Following our conversation, I went and had some conversations about why the changes were made. And the changes were made in the program to make sure—we were fulfilling the statutory obligations with regard to the quality of grantmaking. I think that was a very large portion.

There were two elements. One, the question of making sure we are getting to quality, but the second issue was getting closer to the communities. When all of the money was being funneled

through State grantees, there were also other grantees in States that actually were serving communities as well.

I went to look at our State to see what had happened. And I think in the year before, the State, received a grant of $1.4 million. And in the end, what happened was that two grantees, one was the State and one was another player, came to one, too. So it was a $200,000 reduction, in terms of what the State received.

But the objectives were to try and improve quality and get some grantees that are closer to the local communities.

Senator CAPITO. So is the interpretation that I am making, that the $900,000 cap is just the cap that would go to the actual State government, and if there are other grantees, you could apply through this?

Secretary BURWELL. That is right.

Senator CAPITO. Okay.

Secretary BURWELL. And in West Virginia, we did. We actually were very fortunate. Actually, someone also raised this last year with me, and I had actually asked, could another grantee come forward in the State.

Senator CAPITO. Okay. Because I mean, I think the money needs to flow to the need, obviously. And the quality issue I understand.

Secretary BURWELL. I did follow up on that issue, too. I did ask them about the question of need, because being from West Virginia, I argued that everything, from our type of coal to the population that we have, would be greater need.

Senator CAPITO. Right.

Secretary BURWELL. I think there is difficulty in measurement, and we do need to work and get people to a standard where they are able to measure these things, so we can make decisions better based on that.

Senator CAPITO. Sounds good. Thank you. And we will be following up with you on that.

Secretary BURWELL. Yes. And that's a place where we may need some help, the measurement.

OPIOID ADDICTION

Senator CAPITO. Okay. You mentioned opioid addiction, and what you are doing in that area.

Again, all across America, but we seem to be having a difficult problem with illegal prescription drug abuse and heroin, the rise in heroin, and poisonings, and desperate population.

Help me out here. How can we stop this? I mean, what are you doing in the department?

Secretary BURWELL. When I arrived last June, this was one of the first things that I asked the team to come together on.

There were many things going on in the Department and we have made that into a consolidated strategy with three priorities, because we have a short period of time and we need to be focused. We need to be focused with you all, the Congress. We need to be focused with Governors.

It has three basic elements to it. The first is prescribing. That is where much of this starts. That is the only one that addresses prescription opioids and not heroin. The other two elements address both.

We need to get to a better place, in terms of prescribing. Overprescription is occurring, and that is driving a large part of it. We need to make sure doctors have the right guidance. The head of the AMA was speaking with me about this issue at the SGR event, in terms of they need the right guidance. We need to work on that.

But prescribing is number one.

Number two is access to naloxone. That is an important part of the budget conversation we're having right now, because we need to give the States the money so they can access the naloxone.

Senator CAPITO. Our State just passed a State law to allow them to carry that.

Secretary BURWELL. West Virginia is good. Massachusetts is as well. I'm doing an event next week with Governor Baker, the new Republican Governor in Massachusetts who has made this a big priority, even in his state of the State. We are going to do an event together. They have good things going on there.

The third thing has to do with medicated assisted treatment. Because, sadly, for both heroin and opioids, we have so many people addicted that we are going to have to use medication as part of the treatment.

Those are priorities that I think we all need to work on together.

With regard to our work with Congress, it is about funding, in terms of the conversation we are currently having. It is also about something called buprenorphine, which is also part of treatment, and how we prescribe and how we control prescribing.

But at this point in time, there is general agreement it is a little too controlled, but the changes we need to make I think we need to make in conjunction with Congress.

The other thing is working with the States and making sure they have the prescription drug monitoring plans—PDMPs is what they are referred to—put in place and are strong.

Eventually, we need to make sure those plans are going across States. To us in West Virginia, the border with Kentucky is porous. And if we can't know what that person in Pike County is prescribing, in Mingo County, people are going across.

So those are the kinds of steps we need to take.

Senator CAPITO. Okay, good. Thank you.

Senator BLUNT. Thank you.

Senator Baldwin.

OPIOID ADDICTION

Senator BALDWIN. Thank you, Mr. Chairman and Ranking Member.

I am going to follow on Senator Capito's questions in just a moment. But before I do, I want to thank you, Secretary Burwell, for being here and sharing with the committee, and I am hopeful that we can find relief from the Budget Control Act to allow this subcommittee to draft a bill that provides the funding that HHS needs for its critical programs and to carry out its mission and serve the very people that we all represent in our home States.

And as another side note, as someone who was raised by an NIH-funded scientist, my grandfather, I am certainly a strong supporter of our research and NIH budget. But in particular, knowing the impact that our scarce funding has had on young researchers, I am

especially concerned that the Budget Control Act continues to put our next generation of researchers at risk.

But as I said, I want to focus in on the opioid prescription initiatives that are in your budget. This is an issue that obviously impacts many of our States, I would dare say all of our States.

And so I am interested in hearing a little bit more about the CDC's plan to develop opioid-prescribing guidelines. In particular, I want to ask some specific questions about that.

Number one, we have seen in Wisconsin some particularly tragic cases involving our VA system, a number of tragic deaths of patients who were treated at our VA center in Tomah.

So part of my question is, will these guidelines be applicable to systems like the VA system? And then secondly, guidelines are just that, guidelines. They are not mandates. And so we have had challenges when best practice and, when guidelines have been articulated before, in getting the widespread adoption of those in our medical and prescribing community. Please speak to that, too.

Secretary BURWELL. So with regard to the guidelines, one of the things I think people feel is that they do need more clarity, because there are important issues of pain that need to be treated, and treated with the types of drugs we are talking about.

So we don't want to deny those who depend on these drugs for their daily living. CDC will work with FDA, with NIH, with all the other parts to provide those guidelines.

With regard to the issue that you just articulated with guidelines, this is another space that I actually think we may need to have a conversation about potential legislative help. And that has to do with training, because even if we put the guidelines out, whether or not those existing physicians, and even those coming through, will be trained in these mechanisms and trained in these guidelines, is a question that I think is an extremely important one.

And so how that and where that occurs may be a conversation that we need to continue. That is how we thought about this strategy. That, actually, is a very specific issue that is on our list, to continue to have a dialogue and conversation with you all about.

Senator BALDWIN. I would welcome that follow-up, because the tragedies we have seen in our States, that I have seen in my own State, deserve a response of the utmost seriousness. In fact, I think we are coming very late to this issue.

Your testimony, Secretary Burwell, highlights that, in 2009, total drug overdoses overtook every other cause of injury deaths in the United States. And we have yet to implement a comprehensive strategy.

So in addition to working together on future perhaps legislative measures, what I want to ask you is, how will the administration's proposed initiatives that address this growing nationwide emergency be impacted if your budget request is not funded?

Secretary BURWELL. It will be extremely important. The funding is very important to the States. That is one of the most important parts of this, because it is implemented on the ground. So the funding goes to SAMHSA and CDC. Those are the places where the money is going directly to the States, so having that money available for training and the purchase and use of naloxone.

States are providing the legislation so that more and more people can use it, because there was a question of what type of EMT did you have to be to use it in a number of States. But West Virginia, Massachusetts, and Kentucky, are places making good progress. But even when they make that progress, there are funding issues. So it becomes very important that we make progress this year on these issues.

I also think it is important to reflect that this is done completely in coordination with ONDCP, the Office of National Drug Control Policy in the White House. That is our policy counsel for these issues, to make sure that we are coordinated at HHS, DHS, and Department of Justice. It is mainly us and the Department of Justice that are the two places that interact, because it is mainly law enforcement officials who are the people who need to know how to apply naloxone. They are the people on the scene when there is a drug overdose.

So we need to make sure we are closely tied, and the funds are a part of that.

Senator BLUNT. On your thoughts about legislative help there for connecting these people and places and spaces with what they need to know, do you think you need more authorizing language? Or is this the kind of help you've asked for in the appropriating budget?

Secretary BURWELL. It's not just money. I think it is about how people are willing to implement the guidelines, and make sure that people are trained. The question of continuing medical education and how this touches upon that are the kinds of questions we need to talk about.

I think the AMA and others are thinking through this. But I think it is an important enough issue that we as a Nation at this particular point in time need to make sure that if we have the guidelines, that people are being educated.

Senator BLUNT. Chairman Cochran.

317 IMMUNIZATION PROGRAM

Senator COCHRAN. Mr. Chairman, even though I know this question has already been asked by one of our members, it relates to the immunization program.

Funds are provided to all States to help provide vaccines to those who are not able to buy them, because of their own difficult economic challenges. And there is a majority of funds that are available for childhood vaccinations. And our State has to win the prize as the highest childhood vaccination rate in the country. We are proud of that, because a lot of people spend a lot of time and effort in making that possible.

But it all depends on funding from the program. So in looking at the budget request, we are disturbed that over $50 million in advance funding is recommended. To reduce funding for that amount would be devastating, we think, to the Affordable Care Act.

What is your reaction to that? Do you have any thoughts about what we can do?

Secretary BURWELL. What we have tried to do is design a vaccine budget that included both the children's vaccine and immunization, which actually increased close to $70 million. The increases in the

children's vaccine fund that we made were greater than the decreases in 317. So net-net, it was about a $50 million increase.

What we were trying to do is make sure the places where we did do decreases were for funding for those who were underinsured. And those who were underinsured, because of the Affordable Care Act, that is not occurring, because it is covered.

If you have insurance now, there isn't an uninsurance issue in that you would have to pay a co-pay for your child's vaccination. You no longer will have to do that.

So that is where we were. The cost of the vaccines we were purchasing for use in the facilities that you are talking about, that is what has been reduced. That is because we believe, because of the Affordable Care Act, that is being taken care of through private insurance now.

So we have tried to implement a policy that actually increases overall vaccination funding but decreases it in a place that, because of the Affordable Care Act, those people who were underinsured, had insurance but it didn't pay for this, it now does. That is the objective of the policy.

Senator COCHRAN. Okay. Thank you.

Thanks, Mr. Chairman.

Senator BLUNT. Thank you, Mr. Chairman.

Senator Merkley.

AFFORDABLE CARE ACT COVERAGE

Senator MERKLEY. Thank you very much, Mr. Chair.

Thank you, Madam Secretary, for your testimony.

As I read your testimony, the number that was higher than I had seen before was that 16.4 million Americans who were previously uninsured have now gained health insurance coverage through the different facets of the ACA.

Am I interpreting that correctly?

Secretary BURWELL. Because I always want to be careful with numbers, we think the vast majority of that includes all ACA provisions. But I think the economy has recovered and so some of those people may be people who gained insurance because they have jobs now that have insurance.

So I want to be clear. I think the vast majority gained coverage because of the ACA, and we know that because of the marketplace. But a portion of that could be from something that I think is a very positive thing, which is people who have employer-based care.

Senator MERKLEY. So you go on to have numbers that 11.2 million additional individuals are now enrolled through Medicaid and CHIP. So I assume the large balance, or roughly 5 million of the 11 million who are on the exchange, are folks who previously didn't have insurance, in ballpark numbers?

Secretary BURWELL. Yes. Those have to be derived, because we don't ask anyone when they come in, because there are no pre-existing conditions.

Senator MERKLEY. Yes. Is that roughly the right ballpark of your estimates?

Secretary BURWELL. I am not sure. I don't think we have put out a number of exactly the number in the marketplace who were uninsured.

Senator MERKLEY. Okay, let me continue then.

I was very struck by the statement in the testimony that eight of 10 of those who go to the exchange after tax credits get health insurance for less than $100 per month.

Secretary BURWELL. That is correct.

Senator MERKLEY. So that is out of that 11 million, 80 percent of those.

Secretary BURWELL. That's right.

Senator MERKLEY. Well, it has been a huge change in the uninsured rate in Oregon. Our hospitals are seeing a dramatic drop in the coverage of the uninsured, which gives them more dollars to provide healthcare, and stops the transition in which folks who have insurance had to pay through their rates for folks who do not have insurance, if you will, the uncompensated care.

E-CIGARETTES

I want to turn to another area I have concern about. A year ago, when Commissioner Hamburg was testifying, I raised the issue here of concern over the explosion in the use of e-cigarettes or vaping. These are the electronic devices that vaporize liquid nicotine. It comes in little bottles like this. And I showed these same two bottles, JJuice Scooby Snacks labeled, and JJuice Gummie Bear.

This now has changed dramatically in a single year. We have a new report from the CDC, and it is titled, "E-Cigarette Use Triples Among Middle and High School Students in Just 1 year." It goes on to detail that for high schoolers, it has gone from 4.5 percent to 13.4 percent. Middle schoolers, from 1.1 percent to 3.9 percent, so almost a quadrupling for middle school.

All the CDC studies show that nicotine for adolescent brains is a very bad combination. Thus, it is very important that we regulate this. Back in 2009, Congress gave power to the FDA to regulate flavors and basically all aspects of tobacco products.

So now we are here 6 years later, and we don't have those regulations yet. And I very much appreciated your call to update me on the process.

The process goes from FDA, and then it goes to OMB. And has that transition occurred yet? Is OMB now reviewing? Has FDA shipped its draft final regulation to OMB?

Secretary BURWELL. We are still reviewing the comments at our end, at HHS.

Senator MERKLEY. At HHS. So it has yet to go to the final review within OMB?

Secretary BURWELL. That is correct.

Senator MERKLEY. Or is that simultaneous?

Secretary BURWELL. No, we complete the process of the review.

Senator MERKLEY. You know I was going to ask you about this, but when do you anticipate that will be completed?

Secretary BURWELL. So the question is the overall process of the rulemaking. I think everyone knows that we have a notice of proposed rulemaking. We have a rulemaking that we are in the middle of receiving comments on.

It is our hope that, at some point this summer, we will get to a final stage.

Senator MERKLEY. Well, I hope that it is more than hope. I hope it is a reality. I appreciate your personal efforts to accelerate this process.

But I still am deeply disturbed by the fact that this has taken this long. Had this taken 2 years less, 4 years instead of 6 years, and I don't think anybody thought it needed to take 4 years, then we would have many thousands of high school and middle school students who are not being basically brought into the nicotine addiction world through these flavors designed specifically to appeal to children.

I mean, you have Chocolate and you have Strawberry and you have Gummie Bear and you have Scooby-Doo.

And the statistics show that 90 percent of smokers first began smoking, and I am including vaping in this, as teens. Three out of four teen smokers continue smoking as adults.

In other words, the industry understands that it is in childhood, in the teenage years, that you must secure the addiction, which then has huge consequences for the quality-of-life of the next generation and huge consequences for the cost of our healthcare system.

So this is one of those opportunities to make a dramatic improvement that makes a tremendous amount of sense from every direction. And for every month of delay, it is additional Americans who are damaged.

And it's not just in the smoking. It is also in the poisonings. The poisonings have exploded in the space of time since 2011 until now. It's a 14-fold increase in the poisonings, because these little things, jars look very appealing. They look very appealing, and they are labeled juice and they are called Gummie Bear. It must be something good to drink.

And do you consider it irresponsible that people are making these things and not putting them in childproof bottles?

Secretary BURWELL. With regard to that, I think the question of how everything will be regulated once we get to the deeming, I think those are the questions we are going to have to work to answer and answer quickly.

Senator BLUNT. Time is up.

Senator MERKLEY. Am I over time?

Senator BLUNT. Yes, you are.

Senator MERKLEY. Okay. Thank you very much.

Senator BLUNT. Senator Moran.

Secretary BURWELL. Thank you.

EARLY CHILDHOOD EDUCATION

Senator MORAN. Mr. Chairman, thank you. Congratulations to you and Senator Murray for your leadership on this subcommittee.

And, Secretary Burwell, welcome. Thank you for reaching out to me this week, to see if we could have a conversation on the phone. It's my fault it didn't happen.

But I am very appreciative of the efforts that you make to stay in touch and have conversations.

I think I will have time for a couple of questions. Let me ask first an early childhood education question.

This committee last year allocated $500 million to be used to expand access to infant-toddler services through Early Head Start. And the goal was to expand childcare partnerships. Please tell me about implementation and particularly assure me that rural communities where even licensed childcare is a rare commodity, that they are being considered appropriately for those services.

Secretary BURWELL. We have worked toward implementation, and I think because the program had both Early Head Start and childcare partnerships, that expanded our ability to serve in communities where various types of care would be provided.

We want to make sure we are meeting standards, that are working.

The issue of rural America and these issues of rural access to these types of programs is something I think you probably know is deeply important to me, as someone who participated in Head Start many, many years ago. I understand the limited access that some have to quality early education.

So they're issues that we are working toward. If there are things you are hearing that aren't consistent with that, could you please make sure we know? We haven't heard this issue, so if there is something you have heard from your State, I really would like to know about it.

Senator MORAN. What is the status of implementation?

Secretary BURWELL. Grant-making is occurring. I would have to check on exactly what stage of the grant-making we are in. I can remember the point at which the announcements went out to solicit the grants, but I'm not sure exactly where we are in the process. But we can get back to you on that.

Senator MORAN. I would welcome that.

[The information follows:]

All of the Early Head Start-Child Care Partnership grants were awarded by March, 2015.

The Administration for Children and Families categorized grantees as serving rural areas using the Rural-Urban Commuting Area (RUCA) codes established by USDA and approximated by the University of North Dakota. According to the Census Bureau, urban cities and towns have populations greater than 2,500. RUCA defines rural as an area that does not fall under the Census Bureau urban category.

Each grantee funded under the new EHS–CC grants program must report a main street address. Our review indicates that approximately 90 percent of grantees' main offices are located in an urban zip code and 10 percent of grantees' main offices are located in rural zip codes. We believe that the number of grantees serving rural areas is actually higher because some grantees with main offices located in an urban area serve rural communities, as well. In addition, some grantees are still finalizing the sites of their EHS–CC partners. Once grantees solidify their partnerships and are operational, we will be able to provide urban and rural classifications based on the service area of the grantees. The percentage of EHS–CC grantees in rural areas is similar to the percentage of Head Start grantees in rural areas.

DIETARY GUIDELINES

Senator MORAN. Let me change topics now and talk to you about dietary guidelines. You and Secretary Vilsack, Secretary of Agriculture Vilsack, are charged with developing dietary guidelines. And in that process by which you develop those guidelines, you have an advisory committee, the Dietary Guidelines Advisory Committee.

They have issued a report, and at least to many of us, it is a very controversial report, because it includes, in their recommendations,

and they admit they are taking into account topics outside nutrition and diet, and specifically considering environmental sustainability. So dietary guidelines, which in and of themselves are hard to determine what the right answers are, at least by your advisory committee, is now being expanded to include consideration of environmental sustainability, contrary to the statutory framework by which you and Secretary Vilsack are instructed to develop the guidelines.

I have had conversations with Secretary Vilsack in person in my office, as well as in the hearing in front of the Appropriations Subcommittee on Agriculture, in which he indicated to me that he will color within the lines. By that, I assume he's assuring me that he is going to abide by the statutory framework for those guidelines.

I have also asked him if he's had conversations with you about this topic and what interface is occurring. And my impression is, at this point, that is probably not occurring, at least at the secretarial level.

So my question to you is the same as to the Department of Agriculture. I want to make certain that you agree with the sentiment expressed by the Secretary of Agriculture. I want you to assure me that you intend to, in developing the final guidelines, that you will disregard areas that are outside your instructions in developing the dietary guidelines, that you will stay true to the issues of diet and nutritional science, and not expand the dietary guidelines to something beyond its intended scope.

Secretary BURWELL. Actually, the Secretary and I have spoken. It was about an issue he took up with me, and then I think I received your letter after. We received two different letters.

And we extended the period of comment, because right now, we are in a period where it has been put out.

Senator MORAN. Thank you for that.

Secretary BURWELL. So we have extended that.

I have talked to the Secretary. The first issue that faced us, the process issue, he and I had a chance to talk about it, agree, and very quickly, extend it by 30 days, for the reasons you have stated. We want to see what the comments are, and we want to see what we get back.

When the process comes to HHS, we receive what the advisory committee does. But we will have the full spectrum of our health participants, as well as the surgeon general and the Office of the Assistant Secretary of Health, be part of the conversation as we develop with USDA what will be the final.

With any issue, I will always want to abide by the statute. And as we work to implement that, that is what we will do.

Senator MORAN. I gave you too easy of an out, because, of course, you would say you want to abide by the statute that governs your actions.

So the follow-up question would be, do you share my view or the view, let me say it this way, do you share the view that the dietary guidelines are to be developed around dietary and nutritional science, and nothing more?

Secretary BURWELL. I have to be honest and say I have not reviewed the statute closely enough to be able to answer that question, in the specific way that you have posed it.

As I think I was indicating, the people that are involved, in terms of our issues around science and health, are FDA, and NIH. That is where our sweet spot is. Those are the things that are probably where we have the most——

Senator MORAN. Does that suggest you are going to color within the lines?

Secretary BURWELL. It suggests that I need to read the statute, because I shouldn't answer a question—I apologize—until I actually know what the statute says. I do want to actually abide by the statute.

That is something at this point in the process, I apologize, I haven't gotten to. But I hear and understand that is something you will be following up on.

Senator MORAN. Thank you, Secretary.

Senator BLUNT. Senator Durbin.

NATIONAL INSTITUTES OF HEALTH

Senator DURBIN. Thank you, Madam Secretary, for being here. Let me associate myself with the remarks of Senator Merkley. As we delay this implementation of deeming as to e-cigarettes, more and more children are getting addicted. It is time. So I don't know where this has come to a halt, whether it's in your agency, or OMB, or some other place, but I am going to try to find out and move it along.

Secondly, I met with Dr. Francis Collins a couple of years ago out at NIH. And I said to him, we can't aspire, sadly, to those glory days when Harkin and Specter and Porter doubled the budget for the NIH.

Secretary BURWELL. And I was at OMB.

Senator DURBIN. And you were at OMB.

But what can we do that will make a difference? He said, I would tell you, 5 percent real growth for 10 straight years, he said, will light up the scoreboard. We will provide cures that more than pay for the cost of this research, and alleviate the human suffering involved.

So I have been watching that standard, and I have to tell you that we are falling short of it. Over the last 10 years, we have fallen short by 23 percent of keeping up with inflation at NIH. So the number of grants awarded have been cut in half. That has discouraged researchers from staying.

When I look at the President's budget request for NIH and CDC, I find for each of them roughly a 3 percent increase over last year. If you assume 2 percent inflation—and I understand OMB no longer assumes inflation. I guess that is how they avoid that conversation.

But if you assume 2 percent inflation, you can see the minuscule amount that we are increasing NIH and CDC. I don't ever quote, and I rarely ever praise, Newt Gingrich but I am going to. He ends up writing in the New York Times this week: What are we thinking? We are spending a fortune on all the medical care associated with illness, disease, and yet we are not putting money into the research to alleviate it, as we should.

I would just go a step beyond that and say he fell short of suggesting how we would pay for that, which would be the important ending to his story.

But I just would like to say for the record—I have spoken to Senator Murray, to Senator Blunt, to Senator Alexander, and to others about this—I think it is time for us to step up as Congress and do something truly bipartisan that the American people will applaud, and say we are going to start a commitment of 5 percent plus inflation to key medical research. And we are going to do it on a bipartisan basis, no ifs, ands, or buts about it.

I would just say, for the record, since I am the ranking member on the Defense Appropriations Subcommittee, if there is going to be some conversation about OCO money riding to the rescue of the Pentagon, I want to be part of that conversation, too. But I want to stick to the basic rules that Paul Ryan and Patty Murray came up with, that it is shared equally with non-defense, that we make sure there is money coming back into the nondefense side of the equation, which is so important to Labor-H.

So I hope that the administration will take the same position, that if we can find OCO money to help the Pentagon, I'm for that. But let us not do that at the expense of nondefense.

And I hope, I hope, that we can come to a conclusion that we are going to make our mark in bipartisanship when it comes to biomedical research. Can't think of a more bipartisan issue.

I open it to any comments you'd like to make.

Secretary BURWELL. I would just make two. One is that we, too, believe that, in terms of the numbers and the investments and the tradeoffs and the choices, we need to make those in terms of getting the Nation to function right now but preparing for the future in the way that you are talking about. That is why we make the choices that we do in the President's budget.

And I would also repeat what you just said with regard to the match of increases in defense spending and nondefense spending.

In terms of the health and security of our Nation, I think we saw what happens when Ebola comes to our border and that that is a health and national security issue, but it is one that is funded on the nondefense discretionary side.

So making sure that we keep these two things moving and moving together is something that I think we think is extremely important.

WIC PROGRAM

Senator DURBIN. One other unrelated issue, the WIC program, I believe in it. I hope we can find ways to expand it, make it better.

Do you have any idea what the eligible income is for qualifying for WIC is in the State of Iowa?

Secretary BURWELL. No, I do not.

Senator DURBIN. $90,000 a year. It turns out that when we coordinate the eligibility for Medicaid and WIC, that there is a great disparity among the States as to whether or not you qualify for WIC. I would like to suggest that the statutory standard that we used to have is somewhere near $45,000 as a maximum income that you could qualify for WIC. And because of this coordination of

the Medicaid eligibility and WIC eligibility, there appears to be some gross disparities in some of the States.

Would you look at that?

Secretary BURWELL. I would be happy to. I will work with Secretary Vilsack on these issues. But certainly, this is a number I have never seen, so I want to look into it and understand it.

Senator DURBIN. Thank you.

DIETARY STANDARDS

Senator BLUNT. Thank you. We have a little more time on the vote than we thought we had, so there is time for a second round here, and 11:55 is the scheduled time for the vote. So hopefully, we can work with that time.

On the issue of dietary standards that Senator Moran brought up, he brought that same issue up at the FDA hearing and Commissioner Hamburg stated that she really didn't have a direct role in this and she was an adviser. Today, you have stated that you hadn't really looked at the law yet.

Seems like there is a certain running for the hills here. Secretary Vilsack said that sustainability falls outside the guidelines.

So the one person we have talked to who has looked at the law appears to think that sustainability is not an issue. You may want to argue it should be. All you have to do is change the law for that to happen, but not add it to the law.

So we will be watching that, I am sure.

RISK CORRIDORS

I have a couple of questions for the record. On risk corridor—the risk corridor program, Secretary, the Affordable Care Act—or at least last April. Let me be sure I am right here. The department released guidance stating that the risk corridor program would be implemented in a budget neutral manner.

My impression from the discussions I am hearing now is that somehow the risk corridor program would find revenues somewhere else to make up the difference.

Is that your view?

Secretary BURWELL. When the guidance was put out I was, going between. But with regard to risk corridors, a program that is about making sure we have premium control and downward pressure on premiums, something we all think is important, we believe it will be budget neutral. CBO has scored it as budget neutral.

I think your follow-up question will be, what if it is not? And at this point in time, what we have said is, it is our expectation it will be budget neutral. CBO agrees with us, that it should be budget neutral. Certainly, in this year, what would happen if it weren't is it would fall into the next year, in terms of payments that come in to pay that.

But if in the end, and the end, so we are clear of when the end is, is 2017, there were any issues, I think the insurers believe that commitments have been made. And at that point, one would have to find appropriated funds.

Senator BLUNT. And 2017 is the end of the program?

Secretary BURWELL. Yes. These are temporary——

Senator BLUNT. The theory being, by then, insurance companies should have figured out how to set up the structure and the marketplace and profile.

Secretary BURWELL. That is correct. So with regard to the three Rs, the risk corridors, reinsurance, and risk adjustment, two of those go away on that timetable.

One of them was based on what we used to Medicare Part D that actually didn't go away in that kind of short time frame. But, yes, the idea is, by that time, people will understand the marketplace well enough to get this.

Senator BLUNT. Well, money from discretionary dollars, if that's necessary, would be something we would talk about next year, you would think? Or how would you fill in the gap?

Secretary BURWELL. I don't know that we are going to have any signals. We certainly won't have a signal even about this year until about the end of the summer, and then we will know on the first year, because it is a 3-year program. And right now, all the data is starting to come in.

Senator BLUNT. Designed in the scoring of the Affordable Care Act not to cost money.

Secretary BURWELL. Budget neutral is where it has been, at this point in time.

Senator BLUNT. We will see.

RECOVERY AUDIT CONTRACTORS

On RAC audits, I think what I heard you say in response to Senator Lankford, is one of the things you were looking at was the incentive structure to bring these cases?

Secretary BURWELL. Yes. What we are looking at is in terms of the incentive structure to bring the cases, and to bring any case you wouldn't win. So if you bring a case that you are not going to win, you are not getting anything. If you bring a case that you can't get done in a set period of time, you don't get anything either. So changing some of those incentive structures is important.

Part of the backlog occurs because there is no real cost for a provider to bring all their cases, to appeal so many, because there is only upside, as a provider.

So, the cutoff is very low. I think we need to look at questions of what should the cutoff be for how little money you can appeal for, because of the question of processing.

And then the second question is what are the steps for you, and is there any bar in terms of you appealing everything?

So there is the issue of the RACs. There is the issue of the providers. And there is the issue of our processing. I think for all three of those things we can put in place improvements to both reduce the backlog, which is essential and we have been working with the Congress and have been working with others in a bipartisan way to make those improvements.

The funding will be important. I think you know that it is a judicial process, so we have to have a certain type of appeals judge that can review. So we have a strategy that is about taking administrative actions, things that can get rid of some of the backlog, additional hires that we need to do to process the cases that are before us, and creating prevention in the pipeline so people are not as en-

couraged to do certain types of things, some of it related to RACs, to come into the system.

Senator BLUNT. Are you allowing new cases to be brought while you have this huge backlog out there?

Secretary BURWELL. The issue is divided in terms of the way the legislation was passed and what it banned that RACs could do. There is a time limitation with regard to the RACs. So some things are coming through but portions are not.

Senator BLUNT. Senator Murray.

HEAD START

Senator MURRAY. Thank you.

As you know, this year marks the 50th anniversary of Head Start, which is very exciting. I am really pleased to see the administration's request for a significant investment to make sure that Head Start kids get access to full-day, full-year programs. Some of the early childhood research on this is incredible, that an extended day learning, full-day pre-K, and effective teaching practices, strongly suggesting that the current 3.5 hour day is inadequate.

So this is really an important step in making sure that Head Start prepares our children for success in kindergarten and later in life.

I wanted to ask you, what is the administration doing to improve quality and make Head Start more effective?

Secretary BURWELL. The quality progress has taken place over a number of years. Part of it is that we are reviewing grantees with regard to certain measures of quality, and people are going to have to reapply. We have seen that happen across the country, in terms of those who are not meeting those standards and we are enforcing the quality standards.

That is in the Head Start space. In the childcare space, thank you for the work you all did, in terms of the authorization last year. It's also given us guidance in that space as well.

Senator MURRAY. One of the things I am hearing at home in Washington State is the lack of finding and retaining quality teachers.

What is the department doing to deal with that?

Secretary BURWELL. That is actually a part of the quality standards, in terms of what types of degrees and training that teachers do have. And that is a part of what we are trying to do.

We are seeing some increase in quality, in terms of educational background of teachers. I know that is not the only measure of quality, but we are seeing some progress in that number.

HEALTH CARE FRAUD AND ABUSE

Senator MURRAY. Okay. I think that is important.

My last question, and one that is important, is the fiscal year 2015 Omnibus represented the first time that the Labor-HHS bill utilized the Budget Control Act cap adjustment to fight fraud and abuse in Medicare and Medicaid since it was enacted in 2011. Current data indicates that for every dollar spent to address fraud, $7.60 is recovered by Treasury.

So utilizing that cap adjustment, the Omnibus alone should create over about $5 billion in deficit reduction. I think that's a goal

we all think is critically important. So I don't understand why anyone who wants to cut the deficit would oppose additional dollars for that fund.

I know neither the House nor Senate budget resolution included funds for that. You did. Can you talk about how you can use these targeted resources to help us save money?

Secretary BURWELL. In the budget, we estimate based on the return that we have been seeing and we have used the conservative end of that to do the estimates. It would be about $22 billion, in the proposal from the President, in terms of the savings, if we continue on our path, in terms of Medicare issues.

As I mentioned to you all before we came in, I had the privilege to attend the Sammies, which are the awards for public servants across the entire Federal Government, and those awards went to the people who were pursuing this fraud, and when we can see that kind of success, that cross-government work, we want to do more of it.

We also know the issues of fraud and improper payments in Medicare are a large portion of what we see in the entire government. Having come from OMB and having spent lots of time with Mr. Carper and Dr. Coburn on this issue I am happy to be at a place where hopefully we can bear down and make some progress.

Senator MURRAY. So if the cap adjustment is not allowed to be utilized, we will see an increase in spending?

Secretary BURWELL. We won't see the benefits that we would have gotten. We see those benefits coming every year and we report the numbers every year.

It was 1:8 ratio last year. This past year it has been a one to almost eight, 1:7 ratio, in terms of the return we are getting.

Senator MURRAY. Okay, thank you very much.

Thank you, Mr. Chairman.

MEDICAID EXPANSION

Senator BLUNT. Senator Capito.

Senator CAPITO. Thank you, Mr. Chairman.

I had an additional question. In your statement, you talk about the ACA provides full funding in the Medicaid area all the way through 2016. And then in 2017, the State share then goes to 10 percent or less.

The State of West Virginia, the legislature this year before the expansion had to fill an $80 million hole in their Medicaid budget this year, with no cost of the 140,000 new expansion Medicaid recipients.

I raised this question when this was going through, when we were voting on this, when it was passed. How are the States, my State, our State, going to be able to meet these budgetary expansions that they have taken on themselves because they have expanded Medicaid by 140,000 people when they are already short $80 million this year without expansion?

Secretary BURWELL. I think there are two things, as we think about the answer to the question of how you financially do the Medicaid expansion in a State.

The first is, in Kentucky, they did a baseline study before Governor Beshear expanded Medicaid. He did a follow-up study with

Deloitte and the University of Louisville. It was about 3 months ago and look at what actually has happened with the Medicaid expansion and how you predict that out economically.

In the State of Kentucky, what the study showed is that there would be 40,000 more jobs and $30 billion to the State's coffers, in terms of what the Medicaid expansion would result in, in terms of the economic growth. I think that is one part of the answer.

I think the other part of the answer to the question, which is an important one, has to do with delivery system reform. That has to do with why we are so deeply focused on changing the way care is delivered and the quality of that care.

You and I had an opportunity to talk about the fact that one of the things that drives this is emergency room use. And while the analytics are not strong enough yet, we are starting to see that decrease.

What we are trying to do is to make sure we get to the place where people are not using the most expensive care and using the care in ways that we can save and have quality.

That is an effort that right now we are very focused on with CMS and helping new people who have never been insured before to use the care in ways that, one, they understand how to access the care; two, they understand how to read their bills; and three, they understand that there are tools to keep them healthy.

The diabetes numbers that we are seeing out of States that have expanded, are encouraging.

Senator CAPITO. I would say that all sounds like it is going to solve this problem, but we are talking about, this is on the horizon here. An $80 million budget hole shortfall already without the expansion, you know, you are talking about changing behaviors, and we know it is not going to take a year. It is probably going to be a 5 or 10 year kind of thing.

With the creation of 40,000 jobs, I wish I saw jobs growing in our State, but, unfortunately, that is not happening. We have a lot more people unemployed in higher paid areas, and you know what I am talking about. So we have a real problem here.

I am very concerned about that. By this time, the President and you will be gone, by the time 2017 comes along. And we are going to have a new Governor in our State, and that is going to be a difficult challenge for that Governor.

CHILDREN'S HEALTH INSURANCE PROGRAM

Last question, this should be a simple answer, and I think I am just not seeing the numbers correct. If you expand Medicaid, which we have in West Virginia, and you have asked for an increase in budget in Children's Health Insurance Program, sizable, $3.9 billion, it looks like if I am reading the numbers right. Somebody asked me this, I thought it was a great question and I didn't have the answer. If you are expanding Medicaid, which is pulling in those families and children, wouldn't the cost of the Children's Health Insurance Program go down because a lot of those children are being pulled into Medicaid expansion?

Secretary BURWELL. So the children covered by CHIP are staying in CHIP, and that was part of what the SGR bill just did. So those children are actually not moving over. That's why.

Senator CAPITO. So if you are in CHIP and your family goes into Medicaid, your mom and dad go into Medicaid, you are not required to pull that child into Medicaid with you? You stay in the CHIP program?

Secretary BURWELL. That is correct.

Senator CAPITO. I mean, I worked on the CHIP program as a State representative. I am a big believer in it. I have always voted for expansions of it, because it is important in our State.

So I guess you have answered my question. I guess my follow-up question would be, from an economic standpoint, is it more beneficial to the State and the Federal Government to keep that child in CHIP financially—I am not talking about quality of care and all that because I believe in that—or to go into the Medicaid program? What is less costly?

Secretary BURWELL. That is a piece of work that I think is coming out in the next weeks, in terms of an analysis that we have been asked to do, with regard to the question of does CHIP cost more or does Medicaid cost more?

That is something we are coming out with in the next weeks, as part of the follow-up to the ACA and one of the reports we have been asked to do.

Senator CAPITO. I look forward to seeing the report. Thank you.

KING *v.* burwell

Senator BLUNT. So one last question, then there will be questions for the record. I will have them and others will as well.

But my next thing on my schedule is to go to a meeting of Senators who are talking about what to do based on the result of King *v.* Burwell. In the past, you have said that, really, you are not looking at options if the Court rules that the subsidies aren't valid in a number of States.

Is that still your position?

Secretary BURWELL. I think it is important for me to state we believe we will win the case and that based on both the letter and the intent of the law, that we hold the correct position.

But with regard to if the Court decides for the plaintiffs, at that point the Court will have said we cannot provide those subsidies. And at the point at which that happens, our ability to have authorities to do the subsidies is not something that exists. So the real problem is people lose subsidies, and they then become uninsured, because they were insured because of the affordability. Then the question is of a death spiral in the marketplace because now sicker people are in, and that drives premiums up. And then the question is how that affects States, in terms of costs.

All three of those things result from the loss of subsidies. That's the problem we are trying to solve. And the question is, if the Court says we don't have the authority, how do I have an authority the Court says I don't.

So that is why, when asked about a plan to resolve the massive damage, that's not necessarily something, if the Court makes that kind of decision, that we have seen that we have an authority.

Senator BLUNT. We will see what the Court says.

ADDITIONAL COMMITTEE QUESTIONS

The record will stay open for one week for additional questions.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR ROY BLUNT

PRIVACY OF CONSUMER INFORMATION ON HEALTHCARE.GOV

Question. In January of 2015, the Associated Press published an article stating that HHS was sharing sensitive personal information from applicants of Healthcare.gov. Why was HHS sharing personal consumer information with third party, Internet marketing vendors?

Answer. No third-party tools have had access to names, addresses, Social Security Numbers, or any of the information entered into the application through HealthCare.gov, and no person or group has maliciously accessed personally identifiable information from the site. CMS does not sell or market any information entered into HealthCare.gov.

Your question references the information that was available to third-party tools through a plain-text URL on the Window Shopping feature on the site used to estimate plan costs. The inputs that were unencrypted in the URL included zip code, age, smoking status, pregnancy status, and income. The URL never contained names, addresses, or Social Security Numbers. Immediately after these concerns were raised, CMS began reviewing its use of third-party tools and encrypted the text of the Window Shopping URL. We have found no evidence that any third-party tool misused the anonymous, unverified information entered into the Window Shopping feature. The issues raised about HealthCare.gov's use of third-party tools also prompted CMS to conduct a review of the third-party tools. We removed third-party tools we viewed as redundant.

Additionally, we are in the process of updating our Privacy Impact Assessments (PIAs) and adding new PIAs to further strengthen our privacy procedures. This process and review includes looking to see how we could strengthen our contracts to further safeguard consumer information.

Question. What types of information were shared with the vendors and how was it used?

Answer. Your question references the information that was available to third-party tools through a plain-text URL on the Window Shopping feature on the site used to estimate plan costs. The inputs that were unencrypted in the URL included zip code, age, smoking status, pregnancy status, and income. The URL never contained names, addresses, or Social Security Numbers. Immediately after these concerns were raised, CMS began reviewing its use of third-party tools and encrypted the text of the Window Shopping URL. We have found no evidence that any third-party tool misused the anonymous, unverified information entered into the Window Shopping feature.

Through Healthcare.gov, third-party tools continue to have access to computer information such as browser information or URLs, (as is the case when any computer user visits any Internet site). As is stated in the HealthCare.gov Privacy Policy, the third-party tools collect the following information:

—Internet domains;
—IP addresses;
—Operating systems and browser information;
—Date and time of visits;
—URLs of the pages visited; and
—Addresses of the websites that connected users to HealthCare.gov.

CMS does not sell or rent any information entered into HealthCare.gov. We use third-party tools to better serve our consumers. Through the third-party tools, we work with private sector companies to provide insight into improving site performance, and, during Open Enrollment, conduct outreach efforts to eligible consumers. As is common for consumer-facing websites, we use third-party tools to analyze HealthCare.gov's technical performance and to measure the effectiveness and cost-benefit of our outreach efforts.

Question. Did HHS make consumers aware that their information was going to be shared with a third party for marketing purposes?

Answer. The website's privacy notice, which is publicly posted in plain language, describes the use of the third-party tools. The privacy notice also explains how con-

sumers can "opt out or disable" cookies. The notice is linked through HealthCare.gov's home screen, as well as through several screens throughout the site. We are updating the HealthCare.gov privacy policy to more clearly describe the use of these tools.

Question. Was proper consent obtained to share this type of information?

Answer. The website's privacy notice, which is publicly posted in plain language, describes the use of the third-party tools. The privacy notice also explains how consumers can "opt out or disable" cookies. The notice is linked through HealthCare.gov's home screen, as well as through several screens throughout the site. We are updating the HealthCare.gov privacy policy to more clearly describe the use of these tools.

Question. Is HHS continuing to share this type of information with third parties?

Answer. Immediately after concerns were raised, CMS began reviewing its use of third-party tools and encrypted the text of the Window Shopping URL, so that the inputs for the Window Shopping tool were no longer available to third-party tools through the URL. The issues raised about HealthCare.gov's use of third-party tools also prompted CMS to conduct a review of the third-party tools. We removed third-party tools we viewed as redundant. Additionally, we are in the process of updating our Privacy Impact Assessments (PIAs) and adding new PIAs to further strengthen our privacy procedures. This process and review includes looking to see how we could strengthen our contracts to further safeguard consumer information.

Question. What is HHS doing to protect individuals' privacy?

Answer. We are committed to the protection of consumer information entrusted with us at HealthCare.gov. We are continuing our ongoing review and are looking for additional ways to strengthen our privacy practices. We know that consumers put their trust in us when they visit HealthCare.gov, and that is why we are constantly strengthening our security and privacy controls. CMS developed the Marketplace systems relying on Federal statutes, guidelines, and industry standards that helped us to create standards, processes, and controls for the security and integrity of the systems and the data that flow through them. CMS has implemented measures to protect personal information, including ongoing penetration testing and automated scanning, consistent with FISMA requirements and industry best practices so that security controls are effective in safeguarding consumers' personal information.

GAO REPORT ON SERIOUS MENTAL ILLNESS

Question. GAO recommended that HHS establish a mechanism to coordinate across all the programs that support individuals with serious mental illness and document which programs should be evaluated and how often. HHS disagreed with both of these recommendations stating that staff level coordination and other performance measures are undervalued in the study. How does HHS plan to correct this situation?

Answer. Regarding GAO's recommendation related to coordination, HHS is strongly committed to promoting care coordination for people with serious mental illnesses (SMI). We believe more can be done at all levels to coordinate care for this vulnerable population. HHS is building upon and expanding intra- and inter-agency Federal coordination efforts related to individuals with SMI. In so doing, HHS is leveraging existing Federal coordination methods including the Behavioral Health Coordinating Council (BHCC) Subcommittee on Serious Mental Illness, the Interagency Task Force on Military and Veterans Mental Health, the National Action Alliance for Suicide Prevention, the U.S. Interagency Council on Homelessness, the Re-entry Policy Council, and senior-level communication.

In addition to the existing coordination within HHS and with other Federal partners, SAMHSA and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) will co-lead an effort to address the needs of individuals with SMI and their families, across the Federal Government. This effort will occur in conjunction with the SMI Subcommittee and include current work with the Department of Housing and Urban Development (HUD), the Department of Justice (DOJ), the Department of Defense (DOD), the Department of Veterans Affairs (VA), the Social Security Administration (SSA), the Department of Labor (DOL), the Department of Education (ED) and other Federal departments. SAMHSA and ASPE will work to engage these Departments in this effort, and specifically to identify additional programmatic and policy approaches to address critical, unmet needs for this population.

I agree that evaluation of major programs is essential to understanding impact and improving services for consumers. I am working with ASPE to continue improving our efforts to identify which programs should be evaluated and how they should

be evaluated, including the timing of those evaluations. Decisions regarding which programs to target for evaluation will be informed by a number of factors such as statutory requirements regarding reports to Congress, availability of funds for evaluation, impact, permanence of the program, and size of the program.

2015 DIETARY GUIDELINES FOR AMERICANS

Question. There are significant concerns that the Advisory Committee on Dietary Guidelines has gone outside its purview by recommending Americans eat less meat because it is better for the environment. Do you believe the recommendation to eat less meat falls outside the statutory authority?

Answer. The Department understands there are concerns regarding the recommended level of meat that Americans eat. The 2015 Dietary Guidelines Advisory Committee's current recommendation for Americans to eat less meat is based on improving health and is consistent with previous recommendations. The Advisory Committee did not recommend that Americans eat less meat because it is better for the environment; rather they recommended eating less meat because it is better for the health of Americans.

A recommendation to eat less red meat does not fall outside the statutory authority. We are aware that there is misunderstanding about what the Advisory Report recommends regarding meat consumption and health, with some mistakenly believing that the report recommends that lean meats (including lean red meats) not be included in the 2015 Dietary Guidelines for Americans. This is not the case. To be clear, the Committee's quantitative recommendation for lean meats (see Advisory Report Table D1.32) is identical to the quantitative recommendation in the current Dietary Guidelines for Americans 2010 (see 2010 Dietary Guidelines Appendix 7).

The 2015 Advisory Committee's recommendation to lower intake of meat was in reference to the amount currently consumed—not a recommendation to lower the current Dietary Guidelines quantitative amount—and is consistent with the 2010 Dietary Guidelines recommendation to lower current intake. The Advisory Committee's decision to uphold the recommendation was based on current national intake data (National Health and Nutrition Examination Survey, What We Eat in America, 2007–2010) showing that almost 60 percent of persons aged 1 year and older eat more "meat, poultry, and eggs" than recommended, while approximately 20 percent meet this recommendation, and 20 percent have intake below the recommendation (see Advisory Report Figure D1.21). Thus, the Committee's statement to reduce meat consumption compared to current consumption is within the context of the need to move closer to meeting all food group recommendations and staying within calorie limits, and is unchanged from the current recommendation in the 2010 Dietary Guidelines for Americans.

The Advisory Committee's recommendation to eat less red and processed meat was based on looking at research on various dietary patterns and health outcomes. For example, the Advisory Committee found that patterns associated with a decreased risk of cardiovascular disease are characterized by higher consumption of vegetables, fruits, whole grains, low-fat dairy, and seafood, and lower consumption of red and processed meat, and lower intakes of refined grains, and sugar-sweetened foods and beverages relative to less healthy patterns. In addition as noted in the Advisory Report Figure D2.2 from the American Institute for Cancer Research, colon cancer is strongly linked to consumption of red meat.

Question. It also appears the DGAC decided to go into areas far outside the scope required. For instance, the DGAC decided to address issues such as taxing soft drinks and limiting the types of food and beverages allowed for purchase using SNAP benefits. Do these areas fall outside the statutory authority?

Answer. The 2015 Advisory Committee, similar to several previous advisory committees, included in its review food- and nutrition-related topics that go beyond dietary intake alone but are closely related, such as physical activity and food safety. The 2015 Committee did not review scientific evidence related to the interaction between tax policy and nutrition or health outcomes; rather, it identified taxation as one potential strategy, not a recommendation, to help people meet the Dietary Guidelines for Americans. The purpose of the Dietary Guidelines remains to provide food-based recommendations to help promote health and prevent disease and not to set policies in other realms, such as taxation.

Question. Who will ultimately make the decision as to what is included in the 2015 Dietary Guidelines?

Answer. The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) are in the process of developing the eighth edition of the Dietary Guidelines. The Departments are reviewing the "Scientific Report of the 2015 Dietary Guidelines Advisory Committee" along with comments from Federal agencies

and the public to develop the Dietary Guidelines for Americans, 2015. Nutrition science and policy experts from HHS and USDA write this policy document. It then undergoes external peer review, and review and clearance within the Federal Government prior to being approved and released by HHS and USDA Secretaries.

Question. The DGAC recommends separate labeling of "added sugars," specifying such sugars should be limited to 10 percent of caloric intake. What research supported a listing of sugar as "added?"

Answer. The 2015 Advisory Committee used the definition of added sugars from the Food and Drug Administration's proposed rule on the revision of the nutrition and supplement facts labels (docket no. FDA–2012–N–1210), March 2014. As defined in the Committee's Advisory Report, added sugars are "sugars that are either added during the processing of foods, or are packaged as such. They include sugars (free, mono-and disaccharides), syrups, naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component (e.g., fruit juice concentrates), and other caloric sweeteners. Names for added sugars include: brown sugar, corn sweetener, corn syrup, dextrose, fructose, fruit juice concentrates, glucose, high-fructose corn syrup, honey, invert sugar, lactose, maltose, malt sugar, molasses, raw sugar, turbinado sugar, trehalose, and sucrose."

The 2015 DGAC found that added sugars are a significant source of calories in the American diet. The average intake is 13.4 percent of calories, with children, teenagers and young adults having a greater percentage of calories from added sugars at 15–17 percent. Many of the major food sources of added sugars supply calories but few or no essential nutrients (see Advisory Report figure D1.38).

The DGAC focused its research on the relationship between the consumption of added sugars and health implications. As noted in its Scientific Report, the Advisory Committee concluded that strong and consistent evidence shows that intake of added sugars from food and/or sugar-sweetened beverages is associated with excess body weight in children and adults and with the development of type 2 diabetes in adults. There is moderate evidence that higher intake of added sugars is consistently associated with increased risk of hypertension, stroke, and coronary heart disease in adults and with dental caries in children and adults. The Advisory Committee also found that limiting the amount of added sugar in one's diet is necessary to meet the recommended food group and nutrient needs while staying within calorie limits (see Advisory Committee Report Part D Chapter 6, Question 6). The Advisory Committee's recommendation to reduce added sugars to no more than 10 percent of total calories is consistent with, although more specific than the current Dietary Guidelines for Americans, 2010, which recommends that Americans reduce their intake of calories from added sugars in general and includes limits on "calories from solid fats and added sugars" that can be accommodated in the USDA Food Patterns to meet nutrient needs within calorie limits.

FUNDING FOR MEDICAL COUNTERMEASURES

Question. What is the impact to our Nation's biodefense enterprise if the SRF, BARDA, and SNS are not fully funded?

Answer. The fiscal year 2016 Budget funding level for Project BioShield keeps the program on track to procure twelve new medical countermeasures that will expand our current level of biodefense preparedness. This level will also enable Project BioShield to provide enhanced versions for at least three existing medical countermeasures to maintain our current level of biodefense preparedness for chemical, biological, radiological, and nuclear threats. These project goals are based on the $2.8 billion level, authorized under Pandemic and All Hazards Preparedness Reauthorization Act in 2013. The Project BioShield activities at this level were also outlined in the HHS Medical Countermeasure Multiyear Budget report submitted to Congress in March, 2015.

The fiscal year 2016 Budget level for BARDA would ensure the existing medical countermeasure development pipeline and the continued momentum and benefits of prior year investments, totaling hundreds of millions of dollars. Without BARDA funding, some industry partners may leave the biodefense and infectious disease sector for more secure returns on their investments in the pharmaceutical commercial market.

If the Strategic National Stockpile (within the Centers for Disease Control and Prevention) is not funded at the fiscal year 2016 President's Budget level, our ability to procure, maintain, and replenish existing or new medical countermeasures for biodefense may be inhibited.

In the absence of full funding for these programs, we may not be able to continue replenishing existing medical countermeasures. Second, progress might not be made against existing gaps in preparedness which might otherwise be filled by new med-

ical countermeasures (e.g., nuclear, chemical, and viral hemorrhagic fever). Third, medical countermeasure developers may, in time no longer see the U.S. Government as a reliable partner and may be encouraged to leave the biodefense sector completely.

Question. What activities and MCMs will we lose?

Answer. The U.S. may become increasingly less prepared for biodefense threats for which Project BioShield has already provided medical countermeasures (MCMs) (e.g., anthrax and smallpox). Additionally, the threat gaps to be filled by some of the new MCMs will remain open (e.g., nuclear, chemical, and viral hemorrhagic fever).

At a funding level below the fiscal year 2016 Budget request, Project BioShield may no longer be on track to meet the goals of the fully authorized level of $2.8 billion. If underfunded, BARDA and the Public Health Emergency Medical Countermeasure Enterprise (which is an inter- and intra-Departmental advisory group) would re-prioritize the quantities of new and enhanced MCMs to be purchased, pending available funds. The result of prioritization efforts may be that some threats will be unaddressed (e.g., chemical nerve agents).

Question. How will you pick and choose which MCMs and projects have to be scrapped?

Answer. At a funding level below the fiscal year 2016 Budget request, BARDA and the Public Health Emergency Medical Countermeasure Enterprise will work together to re-prioritize the planned procurement quantities of new and enhanced medical countermeasures (MCMs) based on: (1) threat vulnerability; (2) the availability of a product already in the Strategic National Stockpile to address the threat; (3) the product stage of development; and (4) the cost. For BARDA Advanced Research and Development programs, prioritization for funding will be based on the maturity of the respective MCM program, availability of products procured under Project BioShield and already in the Strategic National Stockpile, threat vulnerability, and cost to develop the MCM for Project BioShield procurement. The launch more effective and universal influenza vaccines, influenza immunotherapeutics, and emerging infectious disease MCMs, would also be curtailed if funding is reduced.

Question. How would ASPR try to soften the impact if SRF, BARDA, and SNS are not fully funded?

Answer. If the fiscal year 2016 President's Budget levels for Project BioShield and the Biomedical Advanced Research and Development Authority (within the Office of the Assistant Secretary for Preparedness and Response) and the Strategic National Stockpile (within the Centers for Disease Control and Prevention) are not fully funded, the Public Health Emergency Medical Countermeasure Enterprise will reassess planned procurements and research priorities within the budget levels, and reprioritize as needed to maintain the highest levels of preparedness.

NATIONAL PREPAREDNESS FOR A PANDEMIC OUTBREAK

Question. Based on our experience to the domestic public health response to Ebola in this country, are we prepared to deal with a pandemic outbreak in the United States?

Answer. For an influenza pandemic, HHS has made great strides since the H1N1 pandemic in 2009 to strengthen the Nation's preparedness for mild to severe pandemics. The number of approved products and requirements for antiviral drugs, ventilators, and respiratory protective devices are evidence of the improved coordination across the entire medical countermeasure continuum.

Below are specific examples of the progress HHS has made towards improved pandemic preparedness:

—CDC has improved global surveillance and virus characterization to detect emergent influenza and other infectious disease strains more quickly.

—CDC and BARDA have established and maintained influenza antiviral drug stockpiles for at least 20 percent of the Nation's population.

—Domestic influenza vaccine manufacturing capacity has increased four to five fold to meet the U.S. demands for pandemic influenza vaccine with new cell- and recombinant-based vaccines, antigen-sparing vaccines using adjuvants, retrofitting of older manufacturing facilities, and building of new manufacturing facilities.

—BARDA established the National Medical Countermeasure Response Infrastructure to develop, manufacture, and test vaccines and therapeutics rapidly and nimbly for pandemic influenza and emerging infectious diseases.

—BARDA established pre-pandemic H5N1 and H7N9 influenza vaccine stockpiles to address needs for critical infrastructure.

—BARDA incorporated technological improvements to speed production of pandemic influenza vaccines (e.g. H7N9 vaccines in 2013) by several weeks through the Influenza Vaccine Manufacturing Improvement Initiative (a partnership between HHS, industry, and academics), to improve vaccine seed candidates, potency assays, and sterility assays for vaccines.
—BARDA supported the development of more effective and universal influenza vaccines that may provide longer and broader cross protection across influenza virus strains and serve as primers for single-dose pandemic influenza vaccines.
—BARDA supported development of new influenza antiviral drug and immunotherapeutic candidates to treat severe influenza cases.
—BARDA supported development of rapid diagnostics to detect influenza in point-of-care and high throughput laboratory settings.
—BARDA improved the systems for distribution, administration, and monitoring of influenza vaccines during pandemics.

HHS/ASPR has also developed a healthcare assessment tool to assess the impact an incident is having on the healthcare delivery system's ability to appropriately care for patients with conventional, contingency, and potentially crisis standards of care. Specifically, the ASPR healthcare assessment tool is a surge strategy designed to assess the increased stress on the healthcare system due to conditions prompted by public health incidents, such as influenza.

In response to the recent Ebola crisis, HHS/ASPR and CDC are working together to fund and establish the National Ebola Training and Education Center (NETEC). The NETEC will increase the competency of healthcare and public health workers and the capability of healthcare facilities to deliver safe, efficient, and effective Ebola patient care through the nationwide, regional network for treatment of Ebola and other infectious diseases. Composed of staff from hospitals that have successfully evaluated and treated Ebola patients in the U.S., and in collaboration with staff from CDC and ASPR, the NETEC will offer expertise, education, training, technical assistance, peer review assessments, recognition, reporting, and, if feasible, certification to regional Ebola and other special pathogen treatment centers, State- and jurisdiction-based Ebola treatment centers, and assessment hospitals.

HHS/ASPR, through the Hospital Preparedness Program's funding opportunity announcement, Ebola Preparedness and Response Activities, is developing a regional approach to caring for future patients with Ebola. This regional approach includes up to ten Ebola treatment centers, which will be designated to serve as Regional Ebola and Other Special Pathogens Treatment Centers, one in each of the ten HHS regions. These regional centers will have enhanced capacity and capabilities to care for patients with Ebola and other highly infectious diseases, and they will be ready within a few hours' notice to receive a patient with confirmed illness from their region, across the United States, or medically-evacuated from outside of the United States, as necessary.

LESSONS LEARNED FROM U.S. DOMESTIC RESPONSE TO EBOLA

Question. There was a systemic public health failure in responding to the Ebola patient in Dallas. What have we learned from our mistakes there?

Answer. HHS is actively working to identify lessons learned related to domestic preparedness and international response to Ebola Virus Disease; the review will focus on the strengths and opportunities for improvement in executing the capabilities required for a successful pandemic-like response. In its role as the Federal leader for health preparedness and response, ASPR has convened the major Department components involved in the response, and will continue to solicit their input. HHS is also looking to utilize a small panel of outside experts, with a chairperson from the Public Health and Medical community, to support the development of formal report. As corrective actions are identified, HHS will work with relevant stakeholders to implement actions to improve response going forward. One of the primary lessons learned from the overall national response to Ebola is that more flexible funding would have improved the response immensely. As such, the fiscal year 2016 President's Budget includes a new $110 million initiative that will provide funds which can be available immediately to responds to an urgent need, including a disease outbreak, a disaster, or an urgent or emergency public healthcare need. This funding could be provided to States quickly in an emergency as well as supplement Federal assets as needed.

RISK CORRIDORS PROGRAM

Question. Why does HHS propose to eliminate the General Provision that this Subcommittee included in the fiscal year 2015 Omnibus to prohibit any discretionary funds for the Risk Corridor program?

Answer. We do not believe the language is necessary based on projections of budget neutrality. The proposal does not reflect a change to the Administration's policy or expectations.

Question. If the Risk Corridor account faces a shortage in its final year, do you intend to use discretionary dollars to make payments to insurers?

Answer. The temporary risk corridor provision in the Affordable Care Act will play an important role in mitigating premium increases in the early years as issuers gain more experience in setting their rates for this new program.

Although we cannot yet calculate the risk corridor payments for plan years 2014 through 2016, current budget projections, including those by the Congressional Budget Office, reflect that money collected from the risk corridor program will be sufficient for payments during the 3 years for which it is authorized. In the unlikely event of a shortfall for the 2016 program year, HHS recognizes that the Affordable Care Act requires us to make full payments to issuers. In that event, HHS will use other sources of funding for the risk corridors payments, subject to the availability of appropriations.

RECOVERY AUDIT CONTRACTORS

Question. Can you provide us with an update on the cross-agency working group?

Answer. The Department created an interagency workgroup comprising representatives from the Centers for Medicare & Medicaid Services, the Office of Medicare Hearings and Appeals (OMHA), the Departmental Appeals Board, and the Office of the Secretary to conduct a thorough review of the Medicare appeals process and develop a series of initiatives to improve the efficiency of the Medicare appeals process and reduce the backlog of appeals. Below are several highlights of the administrative initiatives currently underway and legislative proposals included in the fiscal year 2016 President's Budget. The administrative initiatives and legislative proposals are designed to both reduce the current backlog of pending appeals and resolve claims at the lowest level.

Administrative Initiatives

—Administrative settlement of high volume appeals
—Settlement conference facilitation pilot
—Voluntary statistical sampling pilot
—Prior authorization of power mobility device demonstration
—The Center for Medicare & Medicaid Innovation (CMMI) prior authorization models
—Provider education efforts administered by CMS

Legislative Proposals

—Provide reimbursement for administration from recovery audit program at all HHS appeal levels
—Sample and consolidate similar claims for administrative efficiency
—Establish a refundable filing fee for Medicare Parts A & B Appeals
—Remand appeals to the redetermination level with the introduction of new evidence
—Increase minimum amount in controversy for administrative law judge adjudication of claims to equal amount required for judicial review
—Establish magistrate adjudication for claims with amount in controversy below new ALJ amount in controversy threshold
—Expedite procedures for claims with no material fact in dispute

Question. Specifically, what are they doing to address the RAC issue and current back log at the Office of Medicare Hearings and Appeals?

Answer. The Department has a three-pronged approach to addressing the increasing number of Medicare appeals and the current backlog of claims to be adjudicated. First, invest new resources at all levels of appeal to increase adjudication capacity and implement new strategies to alleviate the current backlog. Second, take administrative actions to reduce the number of pending appeals and more efficiently handle new cases that are entering the appeals process. Third, pursue legislative proposals described in the President's fiscal year 2016 Budget that provide additional funding and new authorities to address this urgent need.

Question. How will the budget request specifically help address the root problem with overaggressive RACs?

Answer. The fiscal year 2016 Budget included a request for statutory authority to conduct Prior Authorization for Medicare Fee-for-service Items. Items that are reviewed through Prior Authorization would be excluded from Recovery Auditor reviews.

CMS has announced a number of future changes to the Recovery Audit Program in response to industry feedback. In the process of procuring new contracts, these changes will result in a more effective and efficient program, including improved accuracy, less provider burden, and more program transparency. A comprehensive list of the Recovery Auditor program improvements can be found at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/RAC-Program-Improvements.pdf.

CDC LABORATORY SAFETY

Question. What is the status of the recommendations put forth by the new advisory committee?

Answer. CDC concurs with the recommendations put forward by the external Laboratory Safety Workgroup of the Advisory Committee to the Director of CDC, has made progress towards implementing them, and reported to the Advisory Committee to the Director on that progress at its April 23, 2015 meeting. The external Laboratory Safety Workgroup is comprised of external experts in the fields of biosafety, laboratory science, and research, and it provides advice, recommendations, and guidance to CDC on establishing an operative and sustainable culture with regards to laboratory safety and quality at CDC. A copy of CDC's presentation to the Advisory Committee to the Director is available on CDC's website here http://www.cdc.gov/about/pdf/lab-safety/cdc-labsafetyupdate-acdpresentation-5-05-2015.pdf. CDC will continue to work toward implementing the recommendations and will continue to engage the external Laboratory Safety Workgroup and the Advisory Committee to the Director, as well as provide updates on the agency's progress.

RAISE EARLY TREATMENT PROGRAM

Question. Are we seeing progress with the RAISE program in States such as Missouri, and is it effectively reaching the population it was designed to help?

Answer. Evidence to date indicates the Recovery After an Initial Schizophrenia Episode (RAISE) program and efforts to further disseminate and implement initial research findings through the Substance Abuse and Mental Health Administration (SAMHSA) Mental Health Block Grant (MHBG) program are benefitting individuals who experience a first episode of psychosis. The Department will continue working to expand the number of community-based settings offering this model of coordinated specialty care.

As you are aware, the National Institute of Mental Health (NIMH) launched the RAISE initiative in 2009 to test the effectiveness of coordinated specialty care programs for individuals experiencing a first episode of psychosis in the United States.[1] Coordinated specialty care is intended to help people recover after an initial psychotic episode and reduce the likelihood of future episodes and long-term disability.

Two research investigations—the RAISE Early Treatment Program and the RAISE Connection Program—were funded to develop, test, and implement coordinated specialty care in community treatment settings. Initial results from the RAISE projects suggest that mental health providers across multiple disciplines can learn the principles of coordinated specialty care, and apply these skills to effectively engage and treat persons in the early stages of psychotic illness.[2] For individuals in the coordinated specialty care program, both symptoms and quality of life improved significantly and more rapidly than those of individuals who received typical community care for first episode of psychosis. Additionally, individuals in the coordinated specialty care program were more likely to be working or going to school. These early findings, combined with the existing evidence supporting early intervention in psychosis, are compelling and have informed the Department's efforts to implement this intervention more broadly.

The fiscal year 2014 Consolidated Appropriations Act provided funds to SAMHSA to support the development of early psychosis treatment programs across the United States through a 5 percent set-aside (approximately $25 million) within SAMHSA's MHBG program. This initiative is now continuing into 2015. SAMHSA and NIMH are working collaboratively on the implementation of this set-aside funding within MHBG, including on the dissemination of RAISE materials, webinars, presentations, and staff trainings.

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[1] See http://www.nimh.nih.gov/health/topics/schizophrenia/raise/index.shtml.

[2] Dixon LB, Goldman HH, Bennett, ME, Wang Y, McNamara KA, Mendon, SJ, Goldstein AB, Choi C–WJ, Lee RJ, Lieberman JA, & Essock SM. (2015). Implementing Coordinated Specialty Care for Early Psychosis: The RAISE Connection Program. Psychiatric Service. PubMed ID 25772764.

In 2013, only 16 States had one or more coordinated specialty care clinics; by September 30, 2015, we estimate that 27 States will have at least one coordinated specialty care clinic as a result of the MHBG set-aside opportunity.

In Missouri, Burrell Behavioral Health, a non-profit community mental health organization, participated in the RAISE Early Treatment Program study between 2010 and 2014. Experience as a RAISE site was a critical factor in developing Missouri's response to the MHBG set-aside opportunity. Missouri is using its MHBG set-aside funds to implement a coordinated specialty care program for first-episode psychosis in its Southwest Block Grant Planning Region. The Burrell facility in Springfield, Missouri was selected to implement this new coordinated specialty care program, due in part to its successful experience in the RAISE Early Treatment Program study.

IMPLEMENTATION OF THE CHILD CARE AND DEVELOPMENT BLOCK GRANT ACT

Question. Last year Congress overwhelmingly passed a reauthorization of the Child Care and Development Block Grant (CCDBG) Act. Before this reauthorization, the Administration was proposing administrative reforms to do many of the same things. Does the Administration have an estimate of how much it will cost States to implement the changes in the CCDBG Reauthorization Act?

Answer. ACF is currently gathering information and input from States and other stakeholders, particularly around the cost of implementing the Child Care and Development Block Grant (CCDBG) reauthorization legislation, including provisions that improve continuity of care, strengthen health and safety standards, mandate comprehensive criminal background checks, and require annual monitoring. The Administration has requested $266 million in CCDBG discretionary funding as part of the fiscal year 2016 Budget to help States begin to implement the new law.

The fiscal year 2016 Budget also includes $82 billion in additional mandatory funding over 10 years to ensure that all low- and moderate-income working families (under 200 percent of the Federal Poverty Level) with children under age four have access to child care assistance that can help them afford high-quality care. By 2025, this investment will provide access to quality care for about 1.15 million additional children under the age of four each year, increasing the total Child Care and Development Fund caseload to a historic high of over 2.6 million children. This mandatory investment also includes funding to maintain access for about 1.5 million children as States implement the changes required by the CCDBG reauthorization. At the same time, this new funding will raise the quality of care for young children currently in care by closing the gap between the low subsidy provided in many child care programs today and the high cost of quality infant and toddler care.

CHILDREN'S HOSPITALS GRADUATE MEDICAL EDUCATION PAYMENT PROGRAM

Question. Currently, the Children's Hospital Graduate Medical Education program provides approximately 45 percent of the funds necessary to train a physician in pediatric care. The President's budget request reduces funding for this program by 62 percent, jeopardizing this critical training. What is the justification for this significant reduction that only pays for direct costs?

Answer. The fiscal year 2016 Budget proposals for graduate medical education target the investments where they are needed most—in primary care (including pediatrics) and certain specialties—and to encourage practice in rural and other underserved areas.

Direct medical education spending includes expenditures related to stipends and fringe benefits for residents; salaries and fringe benefits of supervising faculty; costs associated with providing the graduate medical education training program; and allocated institutional overhead costs. Indirect medical education spending includes expenditures associated with the treatment of more severely ill patients and additional costs associated with the teaching of residents, such as reduced productivity of the hospital staff because they are helping train residents and the processing of additional diagnostic tests that residents may order during their clinical experience. The Budget includes $100 million in discretionary funding, despite tight budgetary constraints, for the Children's Hospitals Graduate Medical Education program to fully support direct medical education expenses at children's hospitals. The Budget prioritizes funding for direct medical education over indirect medical education expenses because of the fact that indirect costs are not well-documented; studies released by MedPAC and other experts indicate that indirect medical education costs may be overstated in certain programs.

The Budget also proposes a new $5.25 billion program (Target Support for Graduate Medical Education) that would expand funding for residency training in pri-

mary care or other high-need specialties, including in pediatrics. Children's hospitals would also be eligible to compete for additional funding under this proposal.

Question. Why is the Department opposed to training more physicians in pediatric care and specialty care?

Answer. We support funding for medical residency training programs for pediatric and specialty care, and are committed to working with Congress to make sure our training hospitals have the resources they need to develop a strong workforce. The funding requested for the Targeted Support for Graduate Medical Education program provides an opportunity for the Children's Hospitals Graduate Medical Education programs and other entities to compete for additional funding to support pediatrics and other high-need specialty residency programs (a total of 13,000 residents over 10 years).

FISCAL YEAR 2016 BUDGET PRIORITIES

Question. The Department's overall request reflects an increase of $4.4 billion. This increase is far greater than anything the Committee could possibly provide within the constraints of the Budget Control Act. Given that it is difficult to discern your priorities with a request that breaks the budget caps, can you discuss what, specifically, are the Department's highest discretionary priorities in fiscal year 2016?

Answer. The Department's fiscal year 2016 Budget proposes $83.8 billion in discretionary budget authority, an increase of $4.8 billion from fiscal year 2015 appropriations. This additional funding will allow the Department to make the investments that are necessary to serve the millions of American people who count on our services every day, while laying the foundation for healthier communities and a stronger economy for the middle class in the years to come. The Budget also further strengthens the infrastructure needed to prevent, prepare for, and respond to future challenges effectively and expeditiously.

The Department's Budget request recognizes our continued commitment to balancing priorities within a constrained budget environment through legislative proposals that, taken together, would save the American people a net estimated $228.2 billion in HHS programs over 10 years. The Budget builds on savings and reforms in the ACA with additional measures to strengthen Medicare and Medicaid, and to continue the historic slow-down in healthcare cost growth. Medicare proposals in our Budget, for example, more closely align payments with the costs of providing care, encourage healthcare providers to deliver better care and better outcomes for their patients, improve access to care, and create incentives for beneficiaries to seek high value services. In order to achieve these goals, it is critical that Congress fully fund the Department's fiscal year 2016 Budget request.

HHS' COMMUNICATIONS EXPENDITURES

Question. Please provide a year-by-year summary of marketing and advertising expenses for the Department over the last three fiscal years, including the primary programs involved in such marketing activities and their primary objectives?

Answer. HHS is responsible for promoting transparency, accountability and access to critical public health and human services information to the public, media, and constituency groups. Many of the Department's communications efforts are embedded in agency operating budgets and program operations, so a breakout of HHS-wide communications activity will take time to compile. HHS will work with Committee staff to provide this information.

The Office of the Secretary's primary objectives include communicating the Department's mission, critical initiatives, and other activities to the general public through various channels of communication; and promoting transparency, accountability, and access to critical public health and human services information to the American people.

OFFICE OF THE SECRETARY COMMUNICATIONS EXPENDITURES

	Fiscal Year			
	2013	2014	2015	2016
Communications	$12,214,168	$11,647,765	$12,447,816	$15,890,147
Travel (Outreach)	30,908	63,659	90,000	77,500
Total	$12,245,076	$11,711,424	$12,537,816	$15,967,647

Includes all funding sources, GDM, ACA, SSF, and individual reimbursable agreements.

SERCO CONTRACT

Question. There have been recent articles highlighting that Serco employees are playing games, reading, or doing nothing at all at the expense of taxpayers. Are these allegations true and what oversight is CMS providing to ensure taxpayer dollars are responsibly used?

Answer. CMS takes seriously any issues involving our contractors, works quickly to address them, and holds them accountable. Over the last year, CMS has put in place additional measures to monitor Serco's performance and worker productivity, and Serco's employees have been cross-trained in multiple tasks to gain additional flexibility and to be as efficient as possible. CMS continues to work with Serco to monitor staffing levels and productivity so staffing can be adjusted.

DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS AND SUPPLIES COMPETITIVE BIDDING PROGRAM

Question. In November 2014 CMS published Final Rule 1614–F. This rule mandates that CMS use the knowledge it gleaned from the competitive bidding program for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) to adjust the fees Medicare pays for certain items in geographic areas not covered by the competitive bidding program. Within a geographic area of competitive bidding only those winning bidders are allowed to service Medicare beneficiaries. Clearly, anyone bidding under such a scenario would have an assumption that suppliers awarded competitive bidding contracts would have access to a greater volume of business. As such, it is logical to assume that they might be willing to accept a lower payment rate in return for higher volume. Providers of these items and services in non-bid areas cannot have such an expectation since any adjustment to the payment rates in non-bid areas does not reduce competition. Adjustments to reimbursement rates in non-bid areas must consider multiple factors including the cost of doing business in a specific geographic area, the existing provider landscape and their ability to service the needs of the market, and the data CMS has collected from its competitive bidding program. Why is CMS only using only competitive bidding pricing information?

Answer. I understand that CMS has been monitoring access and health outcomes data of various types of beneficiaries in the competitive bidding areas, i.e., beneficiaries who have a claim for the product in the month of observation or any of the previous 3 months and patient access groups (beneficiaries with medical conditions that might warrant use of a particular device). CMS has found that payment based on the DMEPOS competitive bidding program has not reduced access to or quality of these items and services. In addition, CMS has not seen any negative impacts since the initial programs, contracts, and payment amounts took effect on January 1, 2011.

CMS will be closely monitoring the impact of the reductions to the fee schedule amounts to determine the extent to which suppliers continue to accept the new amounts as payment in full in all areas where the adjusted fee schedule amounts are used in paying claims. This information, in addition to information on health outcomes in these areas, will allow CMS to assess whether reducing the amounts is causing any negative impacts for CMS beneficiaries.

As your question alludes to, Sections 1834(a)(1)(F)(ii) and (iii) of the Social Security Act requires that payment information be used under the competitive bidding program to adjust the fee schedule amounts for covered items of Durable Medical Equipment in all non-competitive bidding areas beginning January 1, 2016. Additionally, we are required to continuing to make such adjustments to the fee schedule amounts as additional covered items are phased in or information is updated as new contracts are awarded. CMS issued a final rule in November 2014 that sets forth a methodology for adjusting fee schedule payments using information from the Competitive Bidding Program as required by statute.

Question. Congressional intent of the Medicare Improvements for Patients and Providers Act (MIPPA, 2008) was clearly and specifically to exclude complex rehabilitation wheelchairs and accessories from Competitive Bidding because access issues would occur as a result of such reimbursement cuts. This intent was reinforced in a letter recently sent to Acting Administrator Slavitt by 100 members of the House of Representatives. We understand that CMS, through final rule 1614–F, intends to cut reimbursement rates for complex rehabilitation items, despite Congressional intent. What rationale or justification is CMS using to oppose Congressional intent and cut the reimbursement for complex rehab wheelchairs and accessories?

Answer. CMS excluded Group 3 or higher complex rehabilitative power wheelchairs and related accessories furnished in connection with such wheelchairs from

the competitive bidding programs as required by MIPPA. These items are not included in any competitive bidding programs in effect today, and suppliers do not need to compete for contracts for furnishing Group 3 or higher complex rehabilitative power wheelchairs and related accessories.

However, Section 1834(a)(1)(F)(ii) of the Social Security Act mandates adjustments to the fee schedule amounts for durable medical equipment (DME) based on information from the competitive bidding programs. CMS is now establishing more reasonable payment rates for these items and services based on information related to the current costs of furnishing these items and services.

A rule addressing this topic, which was issued in November 2014 (79 FR 66120; CMS–1614–F),finalized a policy that the fee schedule amounts for accessories used with different types of base equipment included in competitive bidding programs would be adjusted based on information from the competitive bidding programs. The Healthcare Common Procedure Coding System (HCPCS) codes that describe wheelchair accessories are used interchangeably on different wheelchair bases. For example, a U1 sealed lead acid battery is the same battery regardless of whether it is used on a standard power wheelchair or a complex rehabilitative power wheelchair. CMS will be using information from the competitive bidding program to adjust the fee schedule amounts for these types of HCPCS codes.

CMS also established a phase-in for the adjustments from January 1, 2016, through June 30, 2016, based on 50 percent of the non-adjusted fee schedule amounts and 50 percent of the adjusted fee schedule amounts. This approach will allow a 6-month transition period where CMS can closely monitor health outcomes data and issues related to access to quality items and services at these lower payment amounts.

MISSOURI MEDICAID AUDIT

Question. The Department of Health and Human Services Inspector General recently conducted an audit in Missouri and found that in a number of cases Medicaid rebates were not collected properly through the Medicaid Drug Rebate Program. The audit states that Missouri owes $34 million to the Federal Government—which is the entire cost of the drugs rather than the amount not collected through the rebate, which is $7 million. Can you explain why Missouri would owe the entire cost of the drug and not just the amount they failed to collect?

Answer. As you noted, the Office of Inspector General (OIG) examined the extent to which Missouri complied with Federal Medicaid requirements for billing manufactures for rebates for physician-administered drugs. The Centers for Medicare & Medicaid Services (CMS) is currently reviewing the OIG audit to gain an understanding of the findings, recommendations and State response. CMS follows a deliberative process for conducting an independent assessment of the OIG report and findings to ensure that CMS is recovering Federal funds appropriately.

RYAN WHITE HIV/AIDS PROGRAM

Question. How many ACA enrollees also receive coverage under Ryan White?

Answer. The Ryan White HIV/AIDS Program data systems collect data on the individuals living with HIV/AIDS served by the program, including their insurance status. Many Ryan White HIV/AIDS Program clients are newly-eligible for coverage under the federally-facilitated Marketplace, State-based or partnership marketplaces, or Medicaid expansion. At the end of 2015, data on insurance coverage for 2014, the first full year of ACA implementation, is anticipated to be available. However, while this information will provide the Department the number of Ryan White clients with healthcare coverage and will distinguish between types of coverage those individuals receive (e.g. Medicaid, Medicare, or private insurance), it will not be able to distinguish whether that coverage is the result of Medicaid expansion or ACA Marketplaces.

The Department is working to understand the impact of the ACA on the Ryan White HIV/AIDS Program and the people it serves, as well as identify the types of medical and wrap-around services provided through the Ryan White HIV/AIDS Program that are not covered or fully covered by Medicaid, Medicare, and private insurance. For example, the Ryan White HIV/AIDS Program also provides oral healthcare, home healthcare, hospice services, medical case management, treatment adherence counseling, psychosocial support services, outreach and a host of other support services that are critical to identifying, linking and maintaining people living with HIV and AIDS in care, which may not be covered by the ACA insurance expansions or other insurance.

OFFICE OF REFUGEE RESETTLEMENT

Question. A comment letter was filed on February 20, 2015 by an array of faith-based organizations that provide caring services for populations like these: the Catholic bishops' migration and refugee services, World Relief, World Vision, National Association of Evangelicals, and Catholic Relief Services. They expressed concern that the Department's commitment to conscience rights is not found in the interim final rule, and they had specific concerns about the vagueness of the preamble. What steps are being taken to prepare a final rule that responds to those concerns?

Answer. ACF released an interim final rule on standards to prevent, detect, and respond to sexual abuse and sexual harassment involving unaccompanied children. This rule comprehensively addresses the issues of sexual abuse and sexual harassment in Office of Refugee Resettlement (ORR) care provider facilities nationwide, and is particularly important, given the unaccompanied youth ORR serves. ORR is firmly committed to protecting children in its custody and treats reports of abuse or mistreatment seriously. The standards build upon existing State and local laws, regulations, and licensing standards.

The interim final rule requires that, among other things, care provider facilities:

—Properly assess and provide follow-up on case management to unaccompanied children who have experienced prior sexual abuse, including referrals to qualified medical and mental health practitioners;

—Provide unaccompanied children who are victims of sexual abuse timely, unimpeded access to emergency medical treatment, crisis intervention services, emergency contraception, sexual transmitted disease prophylaxis, and ongoing medical and mental health evaluations and treatment; and

—Provide female victims of sexual abuse by a male abuser pregnancy tests and timely information about and access to all lawful pregnancy-related medical services.

ACF is committed to continuing the strong partnership with the faith-based organizations that have been critical in delivering services to these vulnerable populations. ORR adheres to the ACF policy on grants to faith-based organizations (found online here http://www.acf.hhs.gov/acf-policy-on-grants-to-faith-based-organizations). In instances where organizations have a conscience objection to requirements in the interim final rule, this policy suggests three specific ways of addressing objections. These are:

—Serve as subgrantees: In many cases, subgrantees do not need to provide every service for which the grantee is responsible as long as the grantee ensures that their overall program provides all required services.

—Apply in a consortium: As long as all clients of the consortium have timely access to all required services, a consortium may be able to divide responsibility for providing those services consistent with each member's principals.

—Notify grantor: In some circumstances, the grantee can notify the Federal office responsible for the grant if a client's needs or circumstances may require services, including referrals, to which the organization has a religious objection. It would then be the Federal agency's responsibility to follow through with the needed service, or transfer the case to another provider.

The policy says that ACF will consider any combination of these approaches and ACF specifically requested comment on other approaches that would accomplish the goal of ensuring that people have access to the full range of services while enabling qualified faith-based organizations to participate in the delivery of those services in a manner consistent with their principals.

The interim final rule was open for public comment through February 23, 2015 and ACF is actively reviewing comments that were received and uploading them onto www.regulations.gov. ACF is carefully considering all comments and is planning to publish a final rule later this year.

U.S. DOMESTIC RESPONSE TO EBOLA

Question. Moving forward, what's the plan?

Answer. HHS has played a critical role in the U.S. Government response to the largest Ebola outbreak in history. Thanks to Congress, a total of $2.8 billion in emergency funding is strengthening the Department's ongoing response to control the Ebola virus outbreak. HHS is working with U.S. Government partners and the international community to ensure that the global response is coordinated and resources are allocated in a way that will improve our capacity to manage future outbreaks. Domestically, States and hospitals have played, and will continue to play, an important role in the ongoing domestic Ebola preparedness and response efforts.

As of April 22nd, HHS has obligated a total of $464 million of the Ebola emergency funding. This funding is supporting specific activities domestically and internationally to improve the detection, prevention, and response to Ebola and other outbreaks by developing new medical countermeasures and strengthening public health and healthcare infrastructures. With input from the public health and hospital communities, the Department has developed a framework for a tiered approach for the U.S. healthcare system, which outlines the different roles facilities play in preparing to identify, isolate, evaluate, and treat possible Ebola patients. Building upon that framework the Department is working to establish a nationwide, regional treatment network for Ebola and other infectious diseases. This network will balance geographic need, differences in institutional capabilities, and account for the potential risk of needing to care for an Ebola patient. Additionally, the Department has established a claims process for reimbursement of treatment and transportation costs for those providers who have treated Ebola patients. Through the Biomedical Advanced Research and Development Authority and the National Institutes of Health, the Department is supporting Ebola vaccine and therapeutics efficacy clinical trials internationally, as well as similar safety trials domestically.

HHS is moving aggressively to manage the Ebola outbreak in West Africa. Ongoing collaboration is occurring with international partners to optimize alignment of policy and planning moving forward. CDC is focused on ending the epidemic in West Africa, assessing the needs of countries at greatest risk for importation, and developing plans for building their capacity to prevent, detect, and respond today and in the future. Currently, CDC has plans in place for $1.2 billion in international response and preparedness and Global Health Security Agenda implementation, and continues to monitor the situation in West Africa and will adjust that plan accordingly if the situation changes. These funds will support networks in West Africa, and other parts of the world, to prevent an outbreak of this magnitude from happening again

From lessons learned in the initial evaluation of the Ebola response, the fiscal year 2016 Budget includes a new proposal for $110 million to support flexibility for immediate emergency response efforts. These funds would be available for quick response to emerging public health crises which are not eligible for Stafford Act funding and for instances where a sufficient emergency supplemental has not yet been provided. Funds could be used for activities such as the rapid deployment of epidemiologists; emergency response activities; purchase of countermeasures; and State and local response. This funding would bolster the Nation's capacity to plan for and manage the response to public health emergencies, including outbreaks of infectious disease that may require both domestic and international response capabilities.

U.S. INTERNATIONAL RESPONSE TO EBOLA IN SIERRA LEONE, GUINEA, AND LIBERIA

Question. How will we address the three countries Ebola recovery plans?

Answer. The Ebola epidemic has highlighted the importance of every country having core public health capacities in place to protect the health and safety of their people. Our first commitment to Liberia, Guinea, and Sierra Leone is to get to zero and stay at zero cases of Ebola. Going forward, we will be working with the three affected countries to identify the priority areas for recovery. These plans will be country-driven, and supported by technical assistance from CDC and other agencies. We are currently working with these countries to assess their public health systems to find out how they have been impacted, where there are gaps, and how to prevent future outbreaks and return public health services to the public. Public health system recovery in these countries will focus on how we prevent future infectious disease threats (by improving systems to prevent, detect and respond) as well as assisting in the re-establishment of public health services including maternal and child health, immunization, malaria prevention, as well as water and sanitation. Within 2015, CDC offices will be established in each of the three countries to engage with the Ministries of Health; cooperative agreements are being established to provide funding from CDC to Ministries of Health and partners for significant ongoing activities; and staff will be put in place to support ongoing operations.

ACA STATE INNOVATION WAIVERS

Question. Recognizing that this authority is not available until 2017, has HHS taken any actions in advance for utilizing this authority under the ACA?

Answer. Final regulations[3] published jointly by the Department of Health and Human Services and the Department of Treasury in February 2012 provided States with guidance about how to apply for a voluntary waiver under this authority. The final regulations set forth a process for States to submit applications and describe what an application from a State must contain. The regulation outlines how public notice and comment will work, including public hearings, to ensure a meaningful level of public involvement, input, and transparency. These requirements were designed to coordinate with the section 1115 requirements, which were published on the same day. Finally, the regulations describe the requirements for post-award reporting and the standards under which post-award monitoring will take place.

Question. If HHS intends to use this provision in the future, what are some of the ideas for implementing it?

Answer. Section 1332 of the Affordable Care Act gives States the option to seek a State innovation waiver to pursue their own innovative strategies to improve healthcare for their residents while retaining the financial protections and insurance coverage achieved by the Affordable Care Act. The Department of Health and Human Services is committed to working with States that express interest in applying for a State innovation waiver.

ACL'S FISCAL YEAR 2016 BUDGET REQUEST

Question. ACL's request for 2016 places significant emphasis on the deployment of evidence-based programs and strategies. What is the Administration's recent history with the identification and dissemination of evidence-based programs to help older adults manage chronic diseases and prevent falls and their return on investment, particularly related to health costs?

Answer. The Administration has a long history of identifying and disseminating cost-effective evidence-based programs to help older adults manage their chronic diseases and/or prevent their risk or fear of falling. This experience includes (1) administering formula grants that must be used only to fund evidence-based programs, (2) awarding and administering discretionary grants for evidence-based chronic disease self-management education programs, (3) awarding and administering discretionary grants for evidence-based falls prevention programs, (4) awarding and administering grants that expand the availability of evidence-based interventions and dementia-capable long term services and supports systems, and (5) managing a rigorous program that evaluates the strength of the evidence behind evidence-based programs.

The Administration on Aging, now a part of the Administration for Community Living, has managed Title III–D of the Older Americans Act, titled Disease Prevention and Health Promotion Services, since 1987. This effort provides formula grants to States and Territories based on their share of the population aged 60 and over to educate older adults about the importance of healthy lifestyles and promote healthy behaviors. These programs can help to prevent or delay chronic disease and disability, thereby reducing the need for more costly medical interventions. In fiscal year 2012, ACL requested and Congress enacted appropriations language requiring States to use these funds only to support proven evidence-based models that enhance the wellness and fitness of the aging community. The same language has been included in each subsequent year's appropriation's language, and is also included in the language proposed for fiscal year 2016. Since the enactment of this language, ACL has provided guidance to States regarding what meets the evidence-based requirement. ACL developed a three tiered set of criteria for defining evidence-based interventions that can be funded with Title III–D funds. For now, States can use funds for programs that meet any of the three levels of evidence. Starting with fiscal year 2017 funds, States can only fund evidence-based programs that meet the highest level of evidence. ACL also provides a cost-chart that lists some of the more common evidence-based programs for States' use, and promote the use of CDC's Compendium of evidence-based programs.

Second, building on ACL's history of supporting evidence-based programs with Recovery Act funds, ACL awarded 22 grants using the Prevention and Public Health Fund to continue these activities. These 3-year grants (now in their third year) are enabling States to provide chronic disease self-management education programs to over 80,000 adults to help them better manage chronic conditions. The funding is not only increasing access to chronic disease self-management education programs, but also fostering the development of comprehensive, integrated delivery systems to

[3] Federal Register, Vol. 77, No. 38, February 27, 2012, Application, Review, and Reporting Process for Waivers for State Innovation, http://www.gpo.gov/fdsys/pkg/FR-2012-02-27/pdf/2012-4395.pdf.

embed and sustain these programs within the long-term supports and services and healthcare systems.

Third, ACL funds falls prevention programs that provide evidence-based programs to help older adults and adults with disabilities prevent falls and reduce their fear of falling, which is a significant risk factor for actually falling. ACL currently funds ten grants to States and four grants to tribes for falls prevention programs using PPHF funding.

Fourth, ACL has years of experience with evidence-based programs and systems that have been proven to help individuals with Alzheimer's disease and their caregivers. These systems are able to identify those with dementia and their family caregivers, understand their unique circumstances, communicate appropriately with them, help them choose services that meet their needs, and provide supports to ease caregiver stress. The most recent grant projects are designed to ensure that States provide people with dementia and their family caregivers with access to a sustainable home and community-based services system that is dementia capable. There are presently fifteen States engaged in projects dedicated to the implementation of dementia-capable services.

Finally, recognizing that the development of evidence-based programs is ongoing, ACL has invested in an Aging and Disability Evidence-Based Program and Practices review process that consists of a rigorous review of evidence-based interventions involving two panels of independent expert reviewers. One set of reviewers assess and rate the quality of research; the other reviewers rate the program on readiness for dissemination. Intervention summaries are made available on ACL's website. Aging and Disability Evidence-Based Program and Practices is one way that ACL is working to improve access to information on evaluated interventions and reduce the lag time between the creation of scientific knowledge and its practical application in the field.

These programs are effective and save healthcare costs. One example of an evidence-based intervention is the New York University Caregiver Intervention, a spousal caregiver support program that in a randomized-control trial delayed institutionalization of persons with dementia by an average of 557 days. Minnesota has translated this intervention and results are consistent with the original study. In addition, in 2013, CMS published a Report to Congress that retrospectively examined pre and post Medicare claims costs for participants in various evidence-based programs that ACL funds. As described in the report, there were statistically significant total Medicare medical cost savings for the following programs: EnhanceFitness, Arthritis Foundation Exercise Program, Arthritis Foundation Tai Chi Program, and Matter of Balance (a falls risk reduction program). The Chronic Disease Self-Management Program from Stanford, which is provided by ACL's Chronic Disease Self-Management grants, showed savings in Medicare inpatient hospital costs.

FUNDING FOR ACL'S FAMILY SUPPORT INITIATIVE

Question. How does this experience translate into the Administration's requests for a Family Support Initiative and modernizing senior nutrition programs?

Answer. The ACL Family Support initiative arose from three motivations: a national crisis in the need for unpaid family caregiving that will be exacerbated by the aging of the baby boomer generation; the recognition that families can draw on and leverage local resources more effectively with better support, information and coordination, thus reducing their dependence on public programs; and a recognition that ACL can expand the experience with developing and maintaining evidence-based programs in the aging policy arena to family supports for people with disabilities. The intent of the Family Support proposal is to build on the success of existing programs that were developed and implemented under the Administration on Aging, requiring State applicants to leverage these existing resources, build partnerships across State agencies and link with private resources as well, utilizing community assets that are available to all citizens in the community. The goal is to create a comprehensive system to support family caregivers in the State that is demographically, economically and culturally appropriate for that State, providing the three prongs of support that research has identified as crucial: knowledge, training and skill development; emotional and social supports; and goods and services, as needed. In addition, ACL proposes to require States to conduct rigorous evaluations, including the use of rapid cycle learning, to make adjustments to their programs to most effectively and efficiently meet the needs of families within the constraints of State resources. The requirements for evaluation and data collection would enable ACL to build an evidence base to support our proposed approach.

On the nutrition front, ACL is committed to working with State and local partners to modernize these services and to ensure that every dollar is spent effectively. As noted in the ACL budget justification, research clearly shows that providing nutrition services improves the health of participants and reduces their need for more expensive medical interventions and institutional care. Translating the knowledge generated by this research into evidence-based models for delivering services at the community level is essential to ensuring the continued efficacy of these programs and improving their efficiency. ACL will build on past experience in evidence-based program development and dissemination to help to prepare these programs to meet the changing demands of seniors as the baby boom generation ages, with priorities to include modernization of infrastructure and delivery systems, increasing meal and service quality, the use of new technology to improve efficiency and communication, and the development of innovative linkages between nutrition sites and health promotion activities.

QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

CRITICAL ACCESS HOSPITALS

Question. I would like to talk about an issue I have raised in previous HHS hearings over the past few years—the importance of Critical Access Hospitals and the proposed cuts to these hospitals contained in the President's 2016 budget request. Again, there are two specific changes proposed by the President's budget, reducing cost based reimbursement from 101 percent to 100 percent and changing the rules to eliminate CAH designations for those hospitals within 10 miles of another hospital.

I am sure you are aware that rural hospitals across the country are struggling to remain open and financially viable. Since 2010, 50 hospitals have closed and 283 are on the brink of closure. Currently, nearly 38 percent of Critical Access Hospitals are operating at a loss. A study by Health Affairs shows that if these changes are implemented that percentage will double to more than 75 percent. At the same time, Critical Access Hospitals account for only 5 percent of Medicare inpatient and outpatient payments. So, these policy changes would result in relatively nominal budgetary savings, but come at a huge cost to rural patients and their communities.

Given the serious challenges these polices would create for many rural hospitals, are you concerned about how they would affect access to healthcare for Americans living in rural communities?

Answer. I am committed to supporting rural America and putting policies into place that strengthen rural communities. The proposals in the President's Budget are carefully targeted to generate savings for the Medicare program without any significant adverse impact on rural access to care. Limiting Critical Access Hospital (CAH) designation to facilities located within ten miles of the nearest hospital will ensure that only facilities whose communities depend upon that facility alone for emergency and basic inpatient care will be designated as CAHs and receive cost-based reimbursement. CMS conducted an analysis of the impact of this proposal on access to services in rural communities.[1] The analysis estimated that a maximum of 47 CAHs, out of a total of 1,339 certified CAHs, might be affected by this proposal. Moreover, facilities losing their CAH designation would not necessarily close. Instead, it is anticipated that many of these CAHs would continue to participate in Medicare as hospitals paid under the applicable prospective payment system, and would continue to provide hospital services to their communities without reliance on CAH designation. Hospitals that transitioned from their CAH status would be eligible for the Hospital Value-based Purchasing Program, which provides financial incentives for high quality of care and improvement in quality.

In the event that some of the potentially affected CAHs were to close, CMS analysis found that there likely is sufficient capacity in nearby facilities to provide the services any closed CAH had previously provided. CMS conducted an analysis of recent Medicare and cost report data for the potentially affected CAHs, as well as for the hospitals located within 10 miles of these CAHs. Overall, the data suggests that there would be no significant issues related to access to inpatient acute care services or skilled nursing services for the communities currently being served by the potentially affected CAHs should the CAH cease to provide services rather than convert its Medicare agreement to participate as a hospital. Additionally, HHS will continue to monitor rural communities to ensure that access to medical care is preserved.

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[1] Centers for Medicare and Medicare Services, Report on Critical Access Hospitals, March 26, 2015.

The President's fiscal year 2016 Budget also proposes changing reimbursement of CAHs to pay them for their actual costs of providing care. This change would generate savings to the Medicare program while protecting access to care by reimbursing CAHs for 100 percent of their costs.

Question. Rural hospitals across the country, including those in Kansas, are facing an ever-increasing amount of Federal regulatory challenges—including meeting the direct supervision requirements for outpatient therapeutic services and keeping pace with their urban counterparts in meeting all of the requirements of the Medicare and Medicaid Electronic Health Care Record Incentive Programs. At the same time, the President has repeatedly called for cuts to Critical Access Hospitals in his budget requests, which are often one of the only sources of healthcare services in a community. Do you think your Department is doing all it can to make sure rural communities maintain access to necessary healthcare services that are vital to their survival and success?

Answer. As you know, being from a small town in West Virginia, rural health is an important priority for me. I am personally committed to and focused on supporting the health of rural communities.

CMS has a number of efforts to improve access to services for rural Medicare beneficiaries. CMS has rural health coordinators at each of our Regional Offices, who meet monthly with participation from CMS central office staff and the Health Resources and Services Administration (HRSA) to discuss emerging issues. Through the Rural Health Open Door Forum, CMS engages with stakeholders to provide current information on CMS programs, answer questions, and learn about emerging rural health issues. Through Medicare's telehealth benefit, Rural Health Clinics, and Critical Access Hospitals (CAHs), CMS is making sure that rural beneficiaries have access to physician and hospital services that may not otherwise be available in their communities. Moving forward, the Center for Medicare and Medicaid Innovation is testing new payment and service delivery models such as Accountable Care Organizations (ACOs) with a focus on how to explore and support efforts to make further strides in improving the quality of care in rural areas.

A key focus of the Department is to increase access for rural Americans to a healthcare provider through health professional training programs. In fiscal year 2014, the Health Resources and Services Administration (HRSA) provided rural health exposure to students through 11,389 training sites in rural communities. In addition, HRSA's primary care, oral health, geriatrics, public health and behavioral health training grants supported 180,401 students from rural areas. The National Health Service Corps supports loan repayment and scholarships for primary care providers, with almost half of the participants serving in rural areas. As of September 30, 2014, 3,529 National Health Service Corps members, or 44 percent of the National Health Service Corps field strength, were working in rural communities and 75 NHSC clinicians were working at CAHs. Half of the nearly 5,000 active NHSC-approved sites are located in rural communities.

Rural communities have also benefited from the collaborative work of the White House Rural Council, which was created in July 2011. The Council is focused on enhancing the ability of Federal programs to serve rural communities through collaboration and coordination. For instance, through the work on the Council, HRSA expanded eligibility for the National Health Service Corps Program to CAHs in 2012. This resulted in 229 CAHs being designated as service sites for National Health Service Corps clinicians. The Council also worked with CMS and HRSA to include a number of rural provisions in a Regulatory Burden Reduction regulation that take into account the unique practice environment for clinicians in rural areas; this regulation was finalized May 2014. Beyond encouraging collaborations among Federal agencies, the Council initiated a public-private partnership with approximately 50 private foundations and trusts that focus on improving rural healthcare.

Question. There is a clear push to move away from fee-for-service medicine and towards quality and value in healthcare. This transition requires hospitals to make up-front investments in health equipment and technology. As we know, many Critical Access Hospitals operate on little to no margins, with limited resources to make capital investments. The cost based reimbursements these hospitals receive are essential to their operations budgets. How are these Critical Access Hospitals supposed to make these investments to facilitate future quality improvements when the Administration's proposals would mean more than three-fourths of these facilities would be operating at a loss?

Answer. Since their creation, Critical Access Hospitals (CAHs) have provided needed hospital services to millions of Medicare beneficiaries. HHS is committed to preserving the CAH program and believes in ensuring that CAHs provide quality care to isolated communities without another nearby source of acute inpatient and emergency care. Last year, CMS finalized a rule that included reforms to Medicare

regulations identified as unnecessary, obsolete, or excessively burdensome on hospitals and other healthcare providers, which will save nearly $660 million annually, and $3.2 billion over 5 years. This rule specifically outlined ways to reduce burdens on rural healthcare providers. For example, a key provision reduces the burden on very small CAHs, as well as Rural Health Clinics and federally Qualified Health Centers, by eliminating the requirement that a physician be held to a prescriptive schedule for being onsite. This provision seeks to address the geographic barriers and remoteness of many rural facilities, and recognizes telehealth improvements and expansions that allow physicians to provide many types of care at lower costs, while maintaining high-quality care.

CMS appreciates the unique challenges that rural providers may confront as they move more towards quality and value. The Innovation Center is uniquely positioned to test and evaluate efforts to identify and address challenges to access and quality of care for rural communities. The Innovation Center is testing two models designed to support Accountable Care Organizations (ACOs) in rural areas. The Advance Payment ACO Model is meant to help entities such as smaller practices and rural providers with less access to capital participate in the Medicare Shared Savings Program. The ACO Investment Model is a new model of pre-paid shared savings that builds on the experience with the Advance Payment Model to encourage new ACOs to form in rural and underserved areas, and to support these types of ACOs that are already participating in the Medicare Shared Savings Program.

FUNDING FOR THE U.S. DOMESTIC RESPONSE TO EBOLA

Question. Are the emergency Ebola funds that Congress appropriated building capacity to address the next emerging infectious disease crisis? Or, are these funds primarily being used to reimburse for expenses incurred since last summer?

Answer. As of April 22nd, HHS has obligated a total of $464 million of the Ebola emergency funding. This funding is supporting specific activities domestically and internationally to improve the detection, prevention, and response to Ebola and other outbreaks by developing new medical countermeasures and strengthening public health and healthcare infrastructures. With input from the public health and hospital communities, the Department has developed a framework for a tiered approach for the U.S. healthcare system, which outlines the different roles facilities play in identifying, isolating, evaluating, and treating possible Ebola patients. Building upon that framework the Department is working to establish a nationwide, regional treatment network for Ebola and other infectious diseases. This network will balance geographic need, differences in institutional capabilities, and account for the potential risk of needing to care for an Ebola patient based on geographic proximity to a funneling airport or diaspora community. Additionally, the Department has established a claims process for reimbursement of treatment and transportation costs for those providers who have treated Ebola patients. Through the Biomedical Advanced Research and Development Authority and the National Institutes of Health, the Department is supporting Ebola vaccine and therapeutics efficacy clinical trials internationally, as well as similar safety trials domestically.

LESSONS LEARNED FROM THE U.S. DOMESTIC RESPONSE TO EBOLA

Question. What lessons have HHS and CDC learned from the Ebola outbreak to make sure State and local health departments are better prepared for the next emerging infectious disease outbreak?

Answer. As of April 22nd, HHS has obligated a total of $464 million of the Ebola emergency funding. This funding is supporting specific activities domestically and internationally to improve the detection, prevention, and response to Ebola and other outbreaks by developing new medical countermeasures and strengthening public health and healthcare infrastructures. With input from the public health and hospital communities, the Department has developed a framework for a tiered approach for the U.S. healthcare system, which outlines the different roles facilities play in preparing to identify, isolate, evaluate, and treat possible Ebola patients. Building upon that framework the Department is working to establish a nationwide, regional treatment network for Ebola and other infectious diseases.

From lessons learned in the initial evaluation of the Ebola response, the fiscal year 2016 Budget includes a new proposal for $110 million to support flexibility for immediate emergency response efforts. These funds would be available for quick response to emerging public health crises which are not eligible for Stafford Act funding and for instances where a sufficient emergency supplemental has not yet been provided. Funds could be used for activities such as the rapid deployment of epidemiologists; emergency response activities; purchase of countermeasures; and State and local response. This funding would bolster the Nation's capacity to plan for and

manage the response to public health emergencies, including outbreaks of infectious disease that may require both domestic and international response capabilities.

CDC IMMUNIZATION PROGRAM FUNDING

Question. The President's fiscal year 2016 budget request contains a $50 million cut to immunization funding at CDC. Considering recent challenges such as the ongoing measles outbreak in many States, how will your Department make sure that local health departments have the resources to work with physicians and other healthcare providers to ensure high rates of immunization?

Answer. As the recent measles outbreak demonstrates, immunization is a critical component of public health infrastructure. Through the Affordable Care Act, nongrandfathered private health plans are now required to cover recommended immunizations without cost-sharing, which has expanded access to this important service. Therefore, the Budget proposes less funding for the 317 immunization program to reflect coverage expansions that reduce the CDC resources needed for vaccine purchase, while providing the infrastructure and program support to maintain record high immunization rates.

The majority of the reduction to the 317 program reflects reduced vaccine purchase. The Budget also maintains funding to recruit and educate networks of immunization providers; provide continual quality assurance; promote public awareness of new and expanded vaccine recommendations; manage vaccine shortages; and respond to vaccine-preventable disease outbreaks. Since 2009, CDC has invested funding to expand the capacity of public health departments to bill health insurers for immunization services in order to expand access for fully-insured individuals in areas where there is not adequate in-network provider coverage. In fiscal year 2016, CDC will continue to support the capacity of public health departments to bill health insurers for immunization services.

In addition, the Budget increases funding for the Vaccines for Children program, a mandatory program that helps families access vaccines. The investment in the Vaccines for Children Program, taken together with CDC's discretionary 317 activities and coverage expansions through the Affordable Care Act, will provide vaccines and the program support to reach uninsured and underinsured populations.

CDC will work collaboratively with its awardees and partners to establish access points at complementary venues such as schools, pharmacies, and retail-based clinics; expand the network of Vaccines for Children providers through recruitment efforts; purchase and deliver vaccine for at-risk populations; and ensure those with insurance have access to immunization services through an in-network provider.

HOME HEALTH CLAIMS

Question. The Affordable Care Act includes a provision that requires a Medicare beneficiary to have a face-to-face encounter with a physician who certifies the need for that beneficiary's Medicare home health services. I understand that this provision aims to make sure Medicare beneficiaries are accurately being referred to the proper care setting, while also reducing the potential for waste, fraud and abuse. However, implementation of this face-to-face requirement has raised many concerns. The rules around what information physicians must document have been unclear and auditors who review the information have applied inconsistent and often conflicting standards on what is deemed "satisfactory." This has resulted in an unprecedented level of home health claim denials and a significant backlog of appeals. As this experience is extrapolated across the sector, I understand that we would expect the number of pending appeals to be in the thousands. In a high percentage of cases, face-to-face claim denials are overturned on appeal. In the meantime, continued unpaid claims—for care that is otherwise medically necessary—are making it hard for smaller home healthcare providers, particularly those in rural and underserved areas, to meet payroll and keep their doors open.

Does your Department have a plan to establish more consistent and uniform auditing rules regarding home health claims?

In the meantime, how does HHS expect to reduce the home health backlog that has resulted from the problems associated with implementation of the face-to-face policy?

Answer. CMS simplified the face-to-face encounter documentation requirements by eliminating the specific face-to-face narrative requirement, in order to reduce administrative burden, and provide home health agencies with additional flexibility. CMS will use documentation from the certifying physician's medical records, and/or the hospital or post-acute facility's medical records, for beneficiaries as the basis for certification of home health eligibility. This simplification was finalized after public comment in the Calendar Year 2015 Home Health Prospective Payment Sys-

tem final rule (79 FR 66031). The use of the template is voluntary and CMS believes the use of clinical templates may reduce burden on the physicians and practitioners who order home health services.

The majority of CMS contractors at the first and second level of the appeals process are processing appeals timely and do not have backlogs. Although there are backlogs at the third and fourth levels, we cannot separately calculate the home health appeals backlog or confirm that the face-to-face requirement is at issue in all of the pending home health appeals without manual reviews of the case files.

The Department has a three-pronged approach to addressing the increasing number of Medicare appeals and the current backlog of claims to be adjudicated. First, invest new resources at all levels of appeal to increase adjudication capacity and implement new strategies to alleviate the current backlog. Second, take administrative actions to reduce the number of pending appeals and more efficiently handle new cases that are entering the appeals process. Third, pursue legislative proposals described in the President's fiscal year 2016 Budget that provide additional funding and new authorities to address this urgent need.

RECOVERY AUDIT CONTRACTOR PROGRAM (RACS)

Question. In response to feedback from hospitals and healthcare providers, the Centers for Medicare & Medicaid Services are making several changes to the Medicare Recovery Audit Contractor (RAC) program. CMS has stated it is "confident that these changes will result in a more effective and efficient program, by enhanced oversight, reduced provider burden and more program transparency."

On August 29, 2014, CMS presented an offer to hospitals to resolve backlogged claims appeals. The period for submitting an intent to participate ended on October 31, 2014. Although over 2,000 hospitals have entered the process, it is unknown how many hospitals will complete the process and choose to accept a global settlement offer. Judge Nancy Griswold, the Chief Administrative Law Judge for the Office of Medicare Hearings and Appeals, noted that, as of July 1, 2014, there were 800,000 pending ALJ RAC appeals. If all of these hospitals were to complete the global settlement process, how many claims would potentially be cleared from the RAC appeal backlog?

Answer. HHS is still in the process of verifying and completing the review of the claims submitted for settlement. Upon completion, HHS can provide this information to the Committee. The Department has a three-pronged approach to addressing the increasing number of Medicare appeals and the current backlog of claims to be adjudicated. First, invest new resources at all levels of appeal to increase adjudication capacity and implement new strategies to alleviate the current backlog. Second, take administrative actions to reduce the number of pending appeals and more efficiently handle new cases that are entering the appeals process. Third, pursue legislative proposals described in the President's fiscal year 2016 Budget that provide additional funding and new authorities to address this urgent need.

The settlement provides an opportunity for the government to reduce the pending appeals backlog by resolving a large number of homogeneous claims in a short period of time. In addition, it allows hospitals to obtain payment now for rendered services, rather than waiting an extended period of time, with the additional risk of not prevailing in the appeals process.

Question. On December 24, 2014, CMS announced another extension of the Part A/B RAC contracts until December 31, 2015, and on December 30, 2014, the agency announced various program improvements that would become effective for the new RAC contracts. According to CMS, the December 30 announcement "marks the beginning of the new Recovery Audit contracts and is the start date of the implementation of many improvements to reduce provider burden and increase transparency in the program." Some of these changes offer real improvements to the RAC process by limiting the scope and burden of the RAC reviews and adjusting RAC incentive structure to encourage quality and accuracy of initial RAC decisions, but the practical significance of the program enhancements will be driven by the establishment of specific standards by CMS, as well as CMS' ability to enforce the program changes. Additionally, due to the delays in awarding the new Part A/B RAC contracts, providers may not experience the implementation of these changes for months or even until 2016.

Not all of CMS's proposed reforms would require contractual changes. For example, CMS could act today to provide audit relief to providers that have low error rates. Why doesn't CMS institute some of these reforms today without waiting for the new contracts, so these improvements can be implemented immediately?

This Subcommittee directed CMS to work with providers to address this issue. Will your Department work with providers on implementation of these various im-

provements, to ensure that they achieve their intended effect of reducing provider burden and increasing transparency?

Answer. CMS has announced a number of future changes to the Recovery Audit Program in response to industry feedback. In the process of procuring new contracts, these changes will result in a more effective and efficient program, including improved accuracy, less provider burden, and more program transparency. A comprehensive list of the Recovery Auditor program improvements can be found at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/RAC-Program-Improvements.pdf.

In addition, CMS will continue to work with providers on implementation of the improvements to ensure they are having the desired effects.

CMS' CIVIL MONETARY PENALTIES

Question. Some skilled nursing facilities in Kansas have told me they have recently noticed a dramatic increase in the dollar amount of fines assessed by CMS when violations are reported. After discussing this matter with some SNF administrators in my State, I understand that CMS has altered its policies regarding the setting of such fines in an attempt to increase consistency across States and facilities. There are concerns that this new policy has created inconsistency of effect on various facilities. Fines are now at such an astronomical level that they cannot reasonably be paid by smaller nursing facilities that provide a critical community service in rural communities.

For example, a county-owned and privately-operated facility in Kansas with capacity for 36 residents located in a town with a population of less than 1,300 is currently facing a fine in excess of $200,000. There may be situations where a fine this large is appropriate and necessary to compel a nursing facility to comply with regulations, but the facilities in my State are generally small, Medicaid providers who most likely do not have the ability to pay a fine of this magnitude. While I recognize the importance of correcting legitimate deficiencies, I am concerned about CMS levying such punitive fines on facilities that have no possible way to pay them and remain viable in the communities they serve.

Can you explain why CMS has increased these fines so dramatically?

Has CMS considered that the effect of fines of this magnitude will be to cause smaller nursing facilities to cease operation?

Does CMS take into account the size and location of a facility when issuing correction plans and related fines for skilled nursing facilities? If so, please explain this process and the factors the agency considers in working with these facilities.

Answer. CMS continues to evaluate policies and procedures pertaining to the imposition of CMPs and is evaluating data in regard to CMPs and other enforcement remedies. CMS has recently finalized guidance (known as the Civil Monetary Penalty (CMP) Analytic Tool) to promote more consistent application of enforcement remedies for skilled nursing facilities, nursing facilities, and dually-certified facilities. The CMP Analytic Tool is a guide CMS Regional Offices use to assess the appropriate type of CMP to be imposed and to calculate the baseline CMP amount for all new enforcement cases when the CMS Regional Office determines that a CMP is an appropriate enforcement remedy.

Beginning on April, 1, 2013, CMS Regional Offices began piloting the CMP Analytic Tool. In an effort to monitor and evaluate the usefulness and effectiveness of this tool, Regional Offices were asked to submit feedback and based on this feedback, we found that the use of this Tool helped with nationally consistent application and imposition of CMPs.

The purpose of the CMP Analytic Tool was not to increase fines; rather, the intent of the CMP Analytic Tool was to promote national consistency and to ensure all statutory and regulatory factors were taken into consideration in determining the CMP amounts. The CMP Analytic tool takes several factors into account. The factors include: scope and severity, past non-compliance, facility history of non-compliance, number of deficiencies, repeat deficiencies, substandard quality of care, facility culpability.

CMS also considers the financial ability of a facility to pay the fine. When determining the CMP amounts, CMS may or may not take into account the size and location of the facility, but does consider the facility's financial status.

QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

FUNDING FOR THE OFFICE FOR THE ADVANCEMENT OF TELEHEALTH

Question. Secretary Burwell, the budget requests level funding of $14.9 million for the Office for the Advancement of Telehealth at the Health Resources and Services Administration. Though Mississippi is considered to have some of the best telehealth capabilities in the country, there is currently no grantee in the State of Mississippi. There are programs throughout the Department of Health and Humans Services that seem to need a reexamination of priorities. What can States like Mississippi do to ensure that they are able to access Federal funds across your Department for the advancement of their innovative healthcare models? What steps has the Department taken to level the playing field for States like Mississippi when it comes to competitive grants?

Answer. The Center for Medicare and Medicaid Innovation in the Centers for Medicare & Medicaid Services supports the development and testing of innovative healthcare payment and service delivery models in different States and communities, including healthcare facilities in Mississippi. For example, thirty-three locations are participating in one of the Bundled Payments for Care Improvement models, which link payments for multiple services beneficiaries receive during an episode of care. The Mississippi Primary Health Care Association received funding through the Strong Start for Mothers and Newborns Initiative, which aims to reduce preterm births and improve outcomes for newborns and pregnant women. It is partnering with eight local organizations to test the Maternity Care Home Approach, which includes enhanced prenatal care including psychosocial support, education and health promotion in addition to traditional prenatal care. Services provided will expand access to care, improve care coordination and provide a broader array of health services. Additionally, Health Care Innovation awardees are conducting work in Mississippi, with projects that include care navigation for Medicare beneficiaries with complex or advanced stage cancer. For more information on Innovation Center activities in Mississippi please visit: http://innovation.cms.gov/initiatives/map/index.html#state=MS.

In addition, there are opportunities for Mississippi to apply for fiscal year 2015 telehealth funding through the Office for the Advancement of Telehealth within the Health Resources and Services Administration. HRSA will soon release a Funding Opportunity Announcement for a telehealth program that focuses on children living in high poverty rural areas. The purpose of the Rural Child Poverty Telehealth Network Grant Program is to demonstrate how telehealth networks can expand access to, coordinate and improve the quality of healthcare services for children living in impoverished rural areas and in particular how such networks can be enhanced through the integration of social and human service organizations. HRSA will award up to three pilot grants for a total annual investment of $975,000 in fiscal year 2015 and $2.9 million over 3 years. Applications from States with high levels of rural child poverty will be very competitive for this program. The Office for the Advancement of Telehealth can work with applicants from Mississippi and other States that may have an interest in this funding opportunity. Furthermore, the Federal Office of Rural Health Policy supports Telehealth Resource Centers, which are centers of telehealth excellence that provide technical assistance to rural communities, healthcare organizations, healthcare networks, and healthcare providers in the implementation of cost effective telehealth programs to serve rural and medically underserved areas and populations. The South Central Telehealth Resource Center serves communities in Mississippi, Arkansas, and Tennessee.

Further, the Office of the National Coordinator for Health Information Technology (ONC) recently announced a Community Interoperability and Health Information Exchange Cooperative Agreement Program for $1,000,000. Earlier this year ONC announced funding opportunities to support healthcare across the continuum including grants to advance interoperability health information technology services to support health information exchange; workforce training to educate healthcare professionals in health information technology; and, funding to support community health peer learning programs.

COMBATING ANTIBIOTIC RESISTANCE

Question. Secretary Burwell, antibiotic-resistant bacteria poses a serious public health risk and economic threat to our country. The Centers for Disease Control and Prevention estimates that 23,000 people die each year in the United States as a direct result of antibiotic-resistant infection and that antibiotic resistance costs taxpayers $20 billion or more per year in additional healthcare costs. There is also growing concern regarding the possible transmission of antibiotic resistance between

animals and humans. Can you speak to the importance of investing in research to combat antibiotic-resistant bacteria, in particular being certain to focus on funding proposals that include both animal and human populations in their research?

Answer. Antibiotics are recognized as one of the greatest advances in the history of medicine, representing extraordinary progress in safeguarding human and animal health. The rising tide of resistance has made medical practitioners and society more aware of the urgent need to reduce the use of antibiotics as much as possible. At the same time, there is need for investing more into new therapeutic approaches, and investigating alternative animal husbandry and patient management practices that will reduce our reliance on antibiotics.

The White House's National Strategy for Combating Antibiotic Resistant Bacteria lists five goals, one of which is to accelerate research into new antibiotics and other therapeutics, including vaccines. In addition, the National Strategy emphasizes the importance of surveillance to track the changing face of resistance and to measure any interventions designed to reduce the prevalence of resistant pathogens. The fiscal year 2016 Budget strongly promotes the field of antibiotics research. The Budget proposes an almost $1 billion investment in fiscal year 2016—nearly double the 2015 funding level—across HHS.

Multiple environmental factors, in addition to antibiotic use in humans and food animals, likely play a role in antibiotic resistance. Research to identify those various factors and the additive or synergistic effects they may have must be conducted to fully understand how antimicrobial resistance changes over time.

In the agriculture sector, research is critical to identifying novel technologies that can be used instead of antibiotics to keep animals healthy. This research includes feed and nutritional supplements, as well as immune modulators, that can strengthen the immune system; therapy using bacteriophage (viruses that infect and kill bacteria) or their gene products; prebiotics and probiotics to promote gut health; therapeutic antibodies and new vaccines. Research in this area can reduce the need for antibiotics in agricultural animal production. This effort does not obviate the need for continuous work to develop new antibiotics, especially those with activity against multi-resistant pathogens. Because there is a need for both new antimicrobial therapies and to promote less reliance on them at the same time, FDA needs to assess challenges associated with their commercialization and use, and provide clear processes to support their development.

FDA is actively working to help accelerate development of antibacterial drugs. Currently, FDA is implementing the new provisions of the Generating Antibiotic Incentives Now Act passed as part of FDASIA, which was enacted to encourage the development of antibacterial and antifungal drugs to treat serious or life-threatening infections. As part of these efforts, the Generating Antibiotic Incentives Now Act provides for an additional 5 years of exclusivity, as well as priority review and fast-track status, for certain products that are designated as Qualified Infectious Disease Products. FDA has granted 71 Qualified Infectious Disease Product designations for 47 unique chemical entities (as of March 26, 2015). These efforts are already having an impact. Within the past year, five new antibacterial drugs with Qualified Infectious Disease Product designation have been approved. In contrast, only five new antibiotics had been approved in the previous 10 year period.

FDA is also working on a number of different activities to facilitate the development of antibacterial drugs so that healthcare providers have new antibacterial drug therapies to treat their patients, including:

—FDA is engaged with public-private partnerships on this topic and has participated in meetings that address a number of important topics associated with the development of new antibacterial drugs. FDA also has held numerous workshops attended by, and sometimes co-sponsored with, external stakeholders, which have served as a venue to discuss the many challenging issues related to antibiotic clinical trial design and development.

—FDA is actively meeting with drug companies that are developing antibacterial drugs to provide advice on antibacterial drug development programs.

—FDA is publishing and updating draft and final guidance documents on recommended clinical trial designs to facilitate development of antibacterial drugs.

QUESTION SUBMITTED BY SENATOR LAMAR ALEXANDER

DUPLICATION OF EARLY CHILDHOOD SERVICES

Question. The Government Accountability Office and others have raised concerns that Federal funding directed towards early childhood programs has resulted in fragmentation and duplication of services. Recognizing the critical role that early

childhood services play in helping kids enter the classroom prepared to learn, can you address how this overlap and duplication affects the delivery of these services? Can you speak to what the Department is doing to minimize duplication, and how the Department can more efficiently use Federal funds to prevent fragmentation?

Answer. The fiscal year 2016 Budget proposes a series of investments across HHS and the Department of Education that will support a continuum of high-quality early learning for children, beginning at birth and continuing to age five. Thanks to bipartisan Congressional support, we have made substantial investments in early learning programs, including $500 million in Early Head Start-Child Care Partnerships. Each of these programs serves a different and complementary role and is structured to collaborate with other early care and education programs in their communities.

There are three main ways that low-income children access quality early learning programs: Head Start, child care programs, and public pre-K. Many communities use funding from each of these programs to meet the needs of children in these areas, such as leveraging child care to ensure children in Head Start or public pre-K have access to a full workday of care. HHS works with our partners at the Department of Education to increase interagency collaboration, including through Preschool Development Grants, to achieve the common goal of increasing access to high-quality care.

This collaboration also includes developing a full report to congress on early childhood coordination and duplication, as required by the Child Care and Development Block Grant Act of 2014.

Furthermore, HHS is also implementing several programs and initiatives at the Federal, State and local level aimed at alignment and reducing duplication, including:

—*Early Head Start-Child Care Partnerships (EHS–CCPs)*.—Early Head Start-Child Care Partnership grants promote greater coordination between Early Head Start and child care, by providing funding to Early Head Start providers to partner with local child care programs. These Partnerships provide more of our Nation's youngest children and their families with access to high quality early learning experiences that will set them up for success in school and beyond. The President's Budget includes an additional $150 million to expand Early Head Start-Child Care Partnerships, which would expand access to high-quality early learning experiences for more infants, toddlers, and their families, while simultaneously enabling greater alignment across the two programs.

—*Technical Assistance*.—We are transforming our technical assistance system to maximize the impact of technical assistance funding in Head Start and child care by aligning efforts across both programs, eliminating any duplication, and ensuring that both programs receive the high-quality technical assistance they need to deliver the best services to children and families.

—*The State Advisory Councils for Early Care and Education (SAC)*.—HHS continues to encourage collaboration and coordination with State Advisory Councils to develop high-quality, comprehensive systems of early childhood development and care and increase alignment between the various sectors within each State that provide services to young children.

—*Intra- and Interagency Partnerships*.—We have brought together several operating divisions within HHS, including the Administration for Children and Families, National Institutes of Health, Centers for Disease Control and Prevention, Health Resources Services Administration, Substance Abuse and Mental Health Services Administration, and others to better coordinate and align our early learning services. In addition, we have worked with several other Federal agencies over the last several months, including Departments of Defense, Agriculture, Housing and Urban Development, and Education, on other initiatives that help align our messages and services, and share lessons learned across programs.

The Department is making important strides in aligning, coordinating, and streamlining early childhood programs and services. However, too many children do not have access to high quality early learning programs that can help them thrive in school and beyond. For example, Early Head Start one of the largest Federal early childhood program for infants and toddlers, only serves about 5 percent of all eligible children. We will continue to work with our partners to minimize duplication and ensure strong alignment so that as many children as possible receive high quality early learning services that set them up to achieve their full potential, improving our Nation's competitive edge in a global economy.

QUESTIONS SUBMITTED BY SENATOR BILL CASSIDY

UNACCOMPANIED CHILDREN

Question. In 2013, DHS, HHS, and other Federal agencies anticipated a sharp increase in unaccompanied minors crossing into the United States from Mexico. Accordingly, HHS was given $1.8 billion to provide the appropriate care for unaccompanied children.

In July, 2014, the Subcommittee on Oversight and Investigations in the Energy and Commerce Committee held a briefing in response to the border crossings being overwhelmed by unaccompanied children and inadequate medical services to help them. During that hearing, Dr. Curi Kim, Director of the Division of Refugee Health in the Office of Refugee Resettlement ORR) at HHS told the subcommittee that she had been transferred two weeks earlier from the Public Health Service. Prior to her transfer, the entire response had been handled by 2 nurses. The hiring of Dr. Kim was part of a ramping up to address the crisis. Please answer the following questions

What is the current volume of services provided by ORR to address the border crisis?

Answer. Unaccompanied children are referred to ORR by another Federal agency, usually the Department of Homeland Security. ORR's statutory obligation is to place the child in the least restrictive setting that is in the best interest of the child, taking into account the child's potential danger to self or others, and risk of flight. Funding provided for unaccompanied children has increased as the number of children has risen. ORR received $948 million for unaccompanied children in fiscal year 2015 compared to $376 million in fiscal year 2013.

ORR's care and placement of unaccompanied children is governed by established child welfare protocols and other Federal statutes and obligations. ORR provides care for the majority of unaccompanied children referred to it through a network of State-licensed, ORR-funded care providers, most of which are located close to the areas where immigration officials apprehend the majority of children. ORR provides various types of care for the children, depending on the particular circumstances of the child involved, ranging from foster care, group homes, and shelters, to secure facilities, and residential treatment centers. ORR's providers operate under cooperative agreements and contracts, and provide children with classroom education, healthcare, socialization/recreation, vocational training, mental health services, help with access to legal services, case management, and facilitate the safe and timely release to a sponsor where appropriate.

As you note in your question, there was a significant increase in the number of unaccompanied children apprehended on the southwest border last year. The Administration responded with an aggressive, coordinated Federal response focused on providing humanitarian care for the children as well as on stronger deterrence, enforcement, foreign cooperation, and capacity for Federal agencies to ensure that our border remains secure. In part due to Administration efforts, including increased border security and assistance to Central American governments to curb the flow of unaccompanied children, the current rate of referrals to ORR is well below fiscal year 2014 levels. In light of these efforts and the recent fall in the number of children placed in ACF's custody, DHS, HHS, and the other agencies responsible for monitoring and serving unaccompanied children expect arrivals to remain stable, though we remain vigilant and are making the appropriate preparations should we experience seasonal increases in migration in the coming months.

ORR is continually evaluating its work on the Unaccompanied Children Program and is committed to implementing appropriate policy and operational improvements, including those that would enable the agency to serve higher than expected caseloads should arrivals unexpectedly increase. For example, since the increase in referrals during the summer of 2014, ORR has bolstered staff capacity in the Unaccompanied Children Program, through the addition of medical staff personnel and the implementation of an Unaccompanied Children Monitoring Team. To ensure unity of effort across the Executive Branch in response to the influx of unaccompanied children across the southwest border last year, the President directed the creation of the Unified Coordination Group, whose members include the Departments of Health and Human Services, Homeland Security, and Defense. Members meet regularly to monitor arrival levels and develop plans to ensure sufficient capacity is available if the number of children increases. ORR has also significantly increased the number of permanent shelter beds as well as the agency's ability to rapidly bring temporary capacity online, if such capacity is needed.

Question. Are all of these services provided at the border or are services continually provided after transfer?

Answer. Unaccompanied children are referred to ORR by other Federal agencies, usually the Department of Homeland Security. ORR does not generally provide services to unaccompanied children at the border. Instead, DHS provides initial services to the unaccompanied children it detains and ORR provides services after the children are transferred to its custody. Care is provided in a network of shelters located in 15 States across the country, where shelter and services are provided until a child is released to the custody of an appropriate sponsor, usually a parent or family member, while their immigration case is adjudicated.

Question. How many unaccompanied children are currently being served by ORR or will be served this year?

Answer. In the first 6 months of fiscal year 2015, a total of 11,706 children were referred to ORR. In part due to Administration efforts, including increased border security and assistance to Central American governments to curb the flow of unaccompanied children, the current rate of referrals to ORR is well below fiscal year 2014. In light of these efforts and the recent fall in the number of children placed in ACF's custody, DHS, HHS, and the other agencies responsible for monitoring and serving unaccompanied children expect arrivals to remain stable, though we remain vigilant and are making the appropriate preparations should we experience seasonal increases in migration in the coming months.

MEDICAID EXPENDITURES PER ENROLLEE

Question. Every year, the nonpartisan Congressional Budget Office projects the Federal cost of adult enrollees in Medicaid. The CBO projects this cost to increase by about 6 percent every year. However, from 2014 to 2015 and after Medicaid expansion, the growth in Medicaid costs for adults is projected to be 36.5 percent.

Now, I understand that the Federal Government pays more to Medicaid Expansion recipients- in fact, 70 percent more to each adult beneficiary. However, the Expansion population only comprises one in five of all Medicaid adult enrollees. Furthermore, these individuals are in better economic situations than the original Medicaid population, which suggests to me they should, on average, be healthier. The numbers simply don't add up here.

Madam Secretary, my question to you is this: We know with every passing year, the Federal Government spends more and more money on each Medicaid enrollee. However, why are Federal costs per Medicaid enrollee going up even more rapidly than anticipated?

Please give a State by State breakdown of average per person Medicaid payments by the Federal Government for the adult non-long-term care, non-disabled population. Please breakout payment on behalf of the dual eligible population separately.

Answer. We understand that there have been important changes to the way in which CBO reports average Federal spending on benefit payments per adult Medicaid enrollee between the February 2013 baseline and the March 2015 baseline. As a result, it is not accurate to say that there has been a 36.5 percent jump in per person Medicaid costs because the increase largely reflects changes in methodology rather than an increase in per person costs.

My understanding is that the March 2015 estimate of Federal spending per adult Medicaid enrollee in fiscal year 2014 reflects only those who were enrolled on an average monthly basis. The February 2013 baseline, on the other hand, reflects those who were enrolled at any time during the fiscal year. The number of enrollees who ever enroll in Medicaid over the course of the year is much higher than the average number who are enrolled each month. As a result, shifting to average monthly enrollment made average spending higher, holding other factors constant. We understand this change was the overwhelming driver of the apparent increase in per adult Medicaid spending from the February 2013 baseline.

There were also two other notable changes between the February 2013 baseline and the March 2015 baseline, the effects of which largely cancel each other out. First, the March 2015 baseline includes the average cost of all enrollees who receive any Medicaid benefit, including partial benefits such as family planning services or premium assistance. In prior years, including the February 2013 baseline, average per enrollee spending was reported only for those who received full Medicaid benefits. Including partial benefit enrollees reduced average spending per enrollee, holding other factors constant. Second, Medicaid enrollment in the newly eligible adult group during fiscal year 2014 was much higher than CBO assumed in the February 2013 baseline. Because the coverage of newly eligible individuals was matched at 100 percent of cost, the average Federal spending on all adults was higher than predicted. In terms of magnitude, the revision for actual enrollment largely offset the revision from including partial benefit enrollees when calculating average spending.

MEDICAID EXPENDITURES PER ENROLLEE NON-DUAL NON-DISABLED ADULTS FISCAL YEAR 2011

State	Total Expenditures ($)	FMAP (%)	Federal Expenditures ($)	Enrollment	Total Per Enrollee Costs ($)	Federal Per Enrollee Costs ($)
AK	208,467,861	68.1	141,891,657	22,237	9,375	6,381
AL	369,755,926	74.7	276,160,670	141,463	2,614	1,952
AR	182,278,647	77.3	140,900,145	84,898	2,147	1,660
AZ	2,239,948,224	72.9	1,632,641,631	374,094	5,988	4,364
CA	4,910,000,444	58.7	2,880,486,830	3,532,286	1,390	815
CO	404,999,401	57.1	231,184,337	111,569	3,630	2,072
CT	1,243,432,041	55.3	687,023,317	214,014	5,810	3,210
DC	400,017,066	73.8	295,073,939	74,798	5,348	3,945
DE	504,625,221	60.0	302,746,622	79,207	6,371	3,822
FL	2,000,368,789	67.6	1,353,071,663	415,745	4,812	3,255
GA	1,329,982,770	71.3	947,963,026	180,783	7,357	5,244
HI	379,470,271	62.0	235,105,589	86,911	4,366	2,705
IA	349,405,237	68.3	238,658,258	132,980	2,628	1,795
ID	190,483,057	75.0	142,856,372	23,026	8,273	6,204
IL	1,702,698,573	57.3	976,349,185	665,019	2,560	1,468
IN	735,222,485	72.1	530,127,190	175,435	4,191	3,022
KS	197,140,360	65.1	128,354,176	37,481	5,260	3,425
KY	676,158,203	77.1	520,994,571	93,716	7,215	5,559
LA	542,102,669	76.3	413,752,570	186,248	2,911	2,222
MA	2,038,976,156	56.9	1,159,527,176	395,633	5,154	2,931
MD	1,290,264,429	57.2	737,560,005	241,132	5,351	3,059
ME	152,375,396	75.0	114,263,492	89,027	1,712	1,283
MI	1,832,846,010	71.5	1,311,198,862	461,118	3,975	2,844
MN	1,323,046,503	56.0	740,515,029	247,604	5,343	2,991
MO	578,490,728	69.9	404,342,525	177,091	3,267	2,283
MS	379,053,250	81.0	307,175,593	82,379	4,601	3,729
MT	80,947,949	79.9	64,660,586	13,084	6,187	4,942
NC	1,247,215,744	70.9	883,952,339	263,326	4,736	3,357
ND	66,984,523	67.7	45,377,384	11,222	5,969	4,044
NE	181,642,330	64.5	117,140,422	30,121	6,030	3,889
NH	68,470,986	58.1	39,780,140	14,700	4,658	2,706
NJ	596,224,059	56.5	336,967,325	124,488	4,789	2,707
NM	625,080,778	76.9	480,834,413	103,384	6,046	4,651
NV	168,544,911	59.2	99,783,166	45,429	3,710	2,196
NY	9,845,134,760	57.5	5,657,875,667	1,826,757	5,389	3,097
OH	2,508,881,299	69.5	1,743,556,007	463,997	5,407	3,758
OK	480,052,216	73.2	351,169,665	134,281	3,575	2,615
OR	969,417,749	69.0	669,253,158	157,102	6,171	4,260
PA	1,736,112,903	62.8	1,089,788,414	396,911	4,374	2,746
RI	162,760,730	59.7	97,130,350	34,350	4,738	2,828
SC	747,374,985	75.7	566,038,147	166,576	4,487	3,398
SD	85,435,845	72.7	62,122,183	14,632	5,839	4,246
TN	2,196,265,388	71.6	1,572,824,967	239,511	9,170	6,567
TX	1,668,973,573	66.6	1,110,774,811	373,828	4,465	2,971
UT	246,176,054	76.7	188,887,883	57,921	4,250	3,261
VA	693,902,213	57.6	399,750,984	118,683	5,847	3,368
VT	254,738,538	65.1	165,791,610	63,931	3,985	2,593
WA	870,748,402	58.2	506,695,203	200,079	4,352	2,532
WI	1,061,801,563	66.7	708,312,475	357,494	2,970	1,981
WV	245,858,758	78.8	193,695,052	40,107	6,130	4,829
WY	62,525,900	59.1	36,936,374	8,381	7,460	4,407

Source: Medicaid Statistical Information System, Annual Person Summary.

Notes:

1. Expenditures and enrollment are calculated using the Medicaid Statistical Information System (MSIS) Annual Person Summary (APS) for 2011, which was the last year that data for most States is available in the APS. 2011 data is incomplete or missing for Florida, Maine, and Montana. 2010 data is provided for these States.

2. MSIS does not contain all Medicaid expenditures, including supplemental payments to providers, prescription drug rebates, and Medicare premiums. These costs may have significant impacts on the total costs and per enrollee costs for these enrollees.

3. The FMAPs in 2010 and 2011 were affected by the temporary FMAP increases provided under the American Recovery and Reinvestment Act of 2009 and the 6-month extension through June 2011. The FMAPs shown reflect the estimated weighted average FMAP for adults' costs in 2010 and 2011.

4. Enrollment is in person-year equivalents (or average annual enrollment).

5. Expenditures and enrollment for adults include persons with basis of eligibility as adult, unemployed adult, and Breast and Cervical Cancer Act adults. Expenditures and enrollment based on the last value for basis of eligibility and dual status in MSIS.

MEDICAID EXPENDITURES PER ENROLLEE DUAL ELIGIBLE NON-DISABLED ADULTS FISCAL YEAR 2011

State	Total Expenditures ($)	FMAP (%)	Federal Expenditures ($)	Enrollment	Total Per Enrollee Costs ($)	Federal Per Enrollee Costs ($)
AK	639,805	68.1	435,477	72	8,886	6,048
AL	1,971,671	74.7	1,472,588	293	6,729	5,026
AR	861,417	77.3	665,869	157	5,487	4,241
AZ	40,716,659	72.9	29,677,343	7,136	5,706	4,159
CA	83,783,764	58.7	49,152,344	19,699	4,253	2,495
CO	1,328,876	57.1	758,557	504	2,637	1,505
CT	27,323,646	55.3	15,096,910	4,942	5,529	3,055
DC	2,442,869	73.8	1,801,991	406	6,017	4,438
DE	1,528,075	60.0	916,759	544	2,809	1,685
FL	7,685,022	67.6	5,198,234	1,729	4,445	3,006
GA	6,640,173	71.3	4,732,872	673	9,867	7,032
HI	1,678,894	62.0	1,040,180	283	5,932	3,676
IA	1,801,987	68.3	1,230,832	581	3,102	2,118
ID	6,276,849	75.0	4,707,442	319	19,677	14,757
IL	46,862,270	57.3	26,871,426	15,127	3,098	1,776
IN	5,767,466	72.1	4,158,592	388	14,865	10,718
KS	705,476	65.1	459,321	176	4,008	2,610
KY	3,680,938	77.1	2,836,243	334	11,021	8,492
LA	3,159,337	76.3	2,411,321	383	8,249	6,296
MA	5,336,800	56.9	3,034,937	670	7,965	4,530
MD	20,083,848	57.2	11,480,626	4,072	4,932	2,819
ME	8,892,064	75.0	6,667,994	4,432	2,006	1,505
MI	136,291,184	71.5	97,501,287	4,542	30,007	21,467
MN	17,875,801	56.0	10,005,166	2,497	7,159	4,007
MO	2,004,571	69.9	1,401,117	453	4,425	3,093
MS	1,083,599	81.0	878,122	169	6,412	5,196
MT	6,931,582	79.9	5,536,893	1,229	5,640	4,505
NC	6,390,175	70.9	4,528,976	802	7,968	5,647
ND	494,823	67.7	335,208	44	11,246	7,618
NE	922,891	64.5	595,169	88	10,487	6,763
NH	3,712,109	58.1	2,156,654	800	4,640	2,696
NJ	17,762,091	56.5	10,038,582	1,266	14,030	7,929
NM	528,439	76.9	406,494	172	3,072	2,363
NV	831,754	59.2	492,421	195	4,265	2,525
NY	96,163,929	57.5	55,264,206	12,901	7,454	4,284
OH	41,234,788	69.5	28,656,263	4,394	9,384	6,522
OK	3,647,313	73.2	2,668,097	371	9,831	7,192
OR	370,102	69.0	255,506	33	11,215	7,743
PA	11,835,648	62.8	7,429,443	1,524	7,766	4,875
RI	2,647,990	59.7	1,580,235	1,327	1,995	1,191
SC	21,607,989	75.7	16,365,207	1,961	11,019	8,345
SD	399,687	72.7	290,621	66	6,056	4,403
TN	31,713,357	71.6	22,711,080	4,166	7,612	5,452
TX	7,110,421	66.6	4,732,296	1,018	6,985	4,649
UT	682,330	76.7	523,543	92	7,417	5,691
VA	2,830,893	57.6	1,630,853	414	6,838	3,939
VT	694,045	65.1	451,706	143	4,853	3,159
WA	3,445,979	58.2	2,005,242	649	5,310	3,090
WI	24,578,667	66.7	16,396,073	5,939	4,139	2,761
WV	1,771,716	78.8	1,395,812	272	6,514	5,132
WY	195,825	59.1	115,681	29	6,753	3,989

Source: Medicaid Statistical Information System, Annual Person Summary.

Notes:

1. Expenditures and enrollment are calculated using the Medicaid Statistical Information System (MSIS) Annual Person Summary (APS) for 2011, which was the last year that data for most States is available in the APS. 2011 data is incomplete or missing for Florida, Maine, and Montana. 2010 data is provided for these States.

2. MSIS does not contain all Medicaid expenditures, including supplemental payments to providers, prescription drug rebates, and Medicare premiums. These costs may have significant impacts on the total costs and per enrollee costs for these enrollees.

3. The FMAPs in 2010 and 2011 were affected by the temporary FMAP increases provided under the American Recovery and Reinvestment Act of 2009 and the 6-month extension through June 2011. The FMAPs shown reflect the estimated weighted average FMAP for adults' costs in 2010 and 2011.

4. Enrollment is in person-year equivalents (or average annual enrollment).

5. Expenditures and enrollment for adults include persons with basis of eligibility as adult, unemployed adult, and Breast and Cervical Cancer Act adults. Expenditures and enrollment based on the last value for basis of eligibility and dual status in MSIS.

QUESTIONS SUBMITTED BY SENATOR SHELLEY MOORE CAPITO

BLACK LUNG CLINICS PROGRAM

Question. Last year, HHS allowed the State of West Virginia and the private West Virginia Primary Care Association to submit duplicative grant applications to essentially evade the newly imposed caps for the Black Lung Clinics program. During the hearing, the Secretary stated the cap was imposed as a result of a review regarding the quality of grant making and the need to get the funds closer to the local communities. By having to split these funds between the two, tens of thousands of dollars of administrative costs were incurred, and thus wasted. If the goal is to improve the quality of the grant, how can this duplication be a better way of managing the process?

Answer. As you know, the incidence rate of black lung disease has increased across the country. To be responsive to this increase and emerging data from the National Institute for Occupational Safety and Health, HRSA modified the funding structure of the Black Lung Clinic program in fiscal year 2014. This structure took into account the $6.7 million appropriation for the program in fiscal year 2014 and set a funding amount that each applicant could apply for in order to ensure that applications from a broad range of areas had the potential to receive support with the available resources. Collaboration was encouraged to better target resources and to best meet existing needs within States and communities. The addition of the primary care association as a grantee in West Virginia has helped broaden the reach of primary care providers across the State, providing opportunities to better serve the target population. In previous years, Kentucky, Illinois and Pennsylvania have all had more than one grantee in their State. In several States, HRSA has witnessed effective partnerships of State and community-based grantees working together to serve those with Black Lung disease. We look forward to continuing to work with you and grantees in West Virginia to promote similar collaboration and ensure that needs of this population are being met.

Question. Wouldn't it make more sense to evaluate grantee applications based on the need for services and the grantees' ability to deliver those services, rather than imposing an arbitrary cap that has led to increased administration costs?

Answer. The application review criteria did require applicants to demonstrate the need for the services and the ability to deliver the services. This took into account the number of miners in each State, along with the quality and breadth of services the applicant intended to provide.

Question. During the budget hearing discussion on the Black Lung Program, the Secretary stated that there was difficulty in measurement and that "We may need some help." What actions does HHS feel Congress should take in this regard to make the necessary improvements?

Answer. There are several data challenges in serving this population. There are data on current or active coal miners, but finding data on the location of retired miners can be more challenging. There are also data on severity of black lung disease, but most of the data are at the national and State level with less available data at the sub-State level. HRSA's funding for the Black Lung Clinic program supports direct services and public health infrastructure rather than for broad data collection. However, HRSA is working with the National Institute of Occupational Safety and Health, located within CDC, and the Mine Safety and Health Administration, located within the Department of Labor, to identify ways to collect more accurate data on miners. We will also work with the current Black Lung Clinic grantees to collect data on miners to better inform the program moving forward.

MEDICARE PART D: PREFERRED COST SHARING NETWORKS FOR PHARMACIES

Question. Last year, as part of a much broader rulemaking, CMS released a proposed regulation that sought to address the issue of access to local pharmacies for rural seniors on Part D drug plans. That larger rule was ultimately withdrawn. Since that time, CMS released a study in December 2014 showing that at least some Part D plans are failing to meet pharmacy access requirements. With the proliferation of preferred pharmacy networks in Medicare Part D, what actions do you believe are necessary to preserve seniors' access to their local pharmacies?

Answer. I understand your concern about access to independent pharmacies, and share your concerns about the transparency of preferred cost sharing networks for pharmacies. CMS is vigorously enforcing the statutory requirement that all pharmacies be offered a contract to participate in a Part D plan's standard network.

Additionally, to help address concerns about beneficiary access to preferred cost sharing pharmacies, the 2016 Medicare Advantage & Part D Final Call Letter an-

nounced several steps to help beneficiaries understand whether a plan offers preferred cost sharing at their local pharmacy prior to selecting that plan.

QUESTIONS SUBMITTED BY SENATOR JAMES LANKFORD

TRANSITION TO ICD–10

Question. The transition to ICD–10 is scheduled to take place on October 1, 2015. The American Medical Association recently wrote a letter to the Acting Director of CMS outlining several concerns and states, in part, that "By CMS's own analysis, one of the most significant risks to moving to ICD–10 is the likelihood for claims processing and cash flow interruptions." The American Health Information Management Association, in its "frequently asked questions" document recommends that CMS "grant 'advance payments' to any physicians that do experience cash flow disruptions as a result of the ICD–10 transition." I understand that CMS has indicated that will use advance payments, but it has not yet made public this policy. Does CMS, in fact, plan to make advance payments? If not, why not? And, if so, please explain the policy and what steps CMS will take to educate providers to ensure they are aware of this policy.

Answer. CMS is ready for ICD–10. And, thanks to many partners—spanning providers, health plans, coders, clearinghouses, professional associations and vendor groups—the healthcare community at large will be ready for ICD–10 on October 1. I appreciate the tremendous efforts and achievements of health professionals as we work together to realize the benefits of ICD–10 and other advances toward the ultimate goal of improving the quality and affordability of healthcare for all Americans.

If providers are unable to code using ICD–10, tailored training, resources, and tools are available specifically to help physicians and their staffs prepare for the ICD–10 transition. There is still time for providers to prepare. CMS has developed multiple tools and resources that are available on the ICD–10 website (http://www.cms.gov/ICD10), including ICD–10 implementation guides, tools for small and rural providers, and general equivalency mappings (ICD–9 to ICD–10 crosswalk).

CMS has the following options for providers who are unable to submit claims with ICD–10 diagnosis codes due to problems with the provider's system. Each of these options requires that the physician be able to code in ICD–10:

—Free billing software that can be downloaded at any time from every MAC;

—Claims submission functionality on the MAC's provider Internet portal; and

—Submitting paper claims, if the requirements of section 1862(h) are met.

I understand that CMS is able to issue advance payments to physicians/suppliers furnishing Part B services only when CMS systems are unable to process valid Part B claims that contain ICD–10 codes beginning October 1, 2015. CMS has no authority to make advance payments if providers are unable to submit a valid claim using ICD–10 codes. Therefore, our focus has been on ensuring that providers receive the education and tools they need to successfully submit claims. CMS has been conducting extensive testing to ensure Medicare claims processing systems are ready for ICD–10.

Question. There are outstanding questions in the physician community concerning the specificity of codes required for inclusion on Medicare claims following the transition to ICD–10. According to the American Medical Association, "CMS officials have stated that, absent indications of potential fraud or intent to purposefully bill incorrectly, CMS will not instruct its contractors to audit claims to verify that the most appropriate ICD–10 code was used." Has CMS conducted any stakeholder and contractor education to ensure that claims are not audited simply for code specificity? If yes, please provide those education materials to the Subcommittee. If no, will CMS conduct stakeholder and contractor education to prevent this kind of audit? If not, why not?

Answer. CMS has issued guidance on the use of unspecified codes for Medicare Fee-for-Service claims. In both ICD–9 and ICD–10, signs/symptoms and unspecified codes have acceptable, even necessary, uses. While specific diagnosis codes should be reported when they are supported by the available medical record documentation and clinical knowledge of the patient's health condition, in some instances signs/symptoms or unspecified codes are the best choice to accurately reflect the healthcare encounter. Each healthcare encounter should be coded to the level of certainty known for that encounter. If a definitive diagnosis has not been established by the end of the encounter, it is appropriate to report codes for sign(s) and/or symptom(s) in lieu of a definitive diagnosis. When sufficient clinical information is not known or available about a particular health condition to assign a more specific code, it is acceptable to report the appropriate unspecified code (for example, a diag-

nosis of pneumonia has been determined but the specific type has not been determined). In fact, unspecified codes should be reported when such codes most accurately reflect what is known.

All the Medicare claims audit programs will use the same approach under ICD–10 as is used under ICD–9. Physicians, like all providers, are expected to code correctly and have sufficient documentation to support the codes selected. For example, if a physician is treating a patient for diabetes, there should be an ICD–1 0 code on the claim for diabetes. The level of specificity of the diabetes code selected will not change the coverage and payment of services in most cases.

RECOVERY AUDIT CONTRACTOR PROGRAM (RACS)

The purpose of an audit is to identify improper payments, not inaccurate coding. Will you direct CMS to issue guidance to its audit contractors to prohibit them from engaging in audits that are only predicated on code specificity? If not, why not? If yes, please provide a copy of that guidance to my office.

Answer. CMS has announced a number of future changes to the Recovery Audit Program in response to industry feedback. In the process of procuring new contracts, these changes will result in a more effective and efficient program, including improved accuracy, less provider burden, and more program transparency. A comprehensive list of the Recovery Auditor program improvements can be found at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/RAC-Program-Improvements.pdf.

Question. In July 2014, GAO found that CMS does not have sufficient information to determine whether its contractors conduct inappropriate duplicative claims reviews and that CMS has conducted insufficient data monitoring to prevent the RACs from conducting inappropriate duplicative reviews. GAO recommended that the Administrator of CMS take the following two actions:

—Monitor the Recovery Audit Data Warehouse to ensure that all postpayment review contractors are submitting required data and that the data the database contains are accurate and complete; and

—Develop complete guidance to define contractors' responsibilities regarding duplicative claims reviews, including specifying whether and when MACs and ZPICs can duplicate other contractors' reviews.

GAO reported that taking these actions would help ensure that Medicare contractors conduct efficient and effective postpayment claims reviews and avoid inappropriate duplication, which is burdensome and costly to providers. In commenting on the July 2014 report on which this analysis is based, HHS stated it would update its guidance for contractors and would explore ways for HHS and contractors to be alerted when data are not entered into the Recovery Audit Data Warehouse within a certain timeframe. Has HHS updated its guidance for contractors? If not, please explain why not, and provide the Subcommittee with a date when we can expect HHS to update its contractor guidance. If yes, please provide a copy of that guidance.

Answer. CMS has been making upgrades to the RAC Data Warehouse to enhance its capabilities. As noted in the GAO report, the RAC Data Warehouse works correctly when data is submitted. CMS has been running reports and validating that the contractors are submitting information about reviews they have on a timely basis to the RAC Data Warehouse. CMS is also working to establish performance metrics and award fee plans for timely and accurate submission of data.

In addition, CMS is currently developing a reporting system that will provide CMS and its medical review contractors a single source of information on Medicare review programs from a provider perspective (e.g. when a provider received education on an issue, which claims were reviewed by the Medicare Administrative Contractor (MAC), Recovery Auditors, or Supplemental Medical Review Contractors). CMS plans to use the Provider Compliance Reporting System (PCRS) to ensure that the same provider/issue is not being reviewed by different medical review contractors at the same time.

CMS will provide guidance on April 27, 2015; via contractor Technical Direction Letter (TDL) designating Recovery Auditors to delay sending Additional Documentation Requests until 60 days after the claim paid date. This delay is necessary to minimize the likelihood of Recovery Auditors reviewing a claim that had a prepayment review done by a MAC. MACs upload their complex reviews to the RAC Data Warehouse using a monthly system-generated file, which excludes the MAC-reviewed claims from potential re-review by a Recovery Auditor.

Question. Please provide a list of all efforts undertaken by HHS to reform the RAC audit process—including draft, proposed, and final guidance or regulations.

Answer. CMS has announced a number of future changes to the Recovery Audit Program in response to industry feedback. In the process of procuring new contracts, these changes will result in a more effective and efficient program, including improved accuracy, less provider burden, and more program transparency. A comprehensive list of the Recovery Auditor program improvements can be found at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/RAC-Program-Improvements.pdf.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

IMPLEMENTATION OF THE CHILD CARE AND DEVELOPMENT BLOCK GRANT ACT

Question. Congress reauthorized the Child Care and Development Block Grant last year, and we included many new provisions designed to improve the safety and quality of care, such as greater enforcement of licensing standards. These new requirements will come with new costs for States. I understand that a large part of the President's request—$266 million—would provide States with additional resources to meet these new requirements. How are you working with States to make sure that, as they implement the new quality and safety provisions, children and families don't lose access to child care? What would be the impact if CCDBG did not get additional resources in 2016?

Answer. The Administration for Children and Families and the Office of Child Care are committed to supporting States by providing technical assistance and guidance on key issues, including on ways to promote access, as States implement the new Child Care and Development Block Grant reauthorization. State Lead Agencies are currently developing State plans for Federal fiscal years 2017–2019, which are due March 1, 2016. HHS provided an extension of the deadline (which was originally July 1, 2015) at the request of State Administrators to allow time for thoughtful planning and partnership-building across the early childhood agencies in States. Currently, we have policy guidance and relevant resources available at www.acf.hhs.gov/programs/occ/ccdf-reauthorization. In order to help States develop strategies around the specifics of new policies required by reauthorization, we have also compiled a set of technical assistance resources available at https://childcareta.acf.hhs.gov/ccdf-reauthorization. Some of the technical assistance resources aim to help States implement the new quality and safety provisions in an efficient, cost-effective manner, with the goal of ensuring that sufficient resources remain to promote access to child care services. For example, HHS recently published a white paper on Innovation in Monitoring in Early Care and Education that outlines options for States, including approaches that provide greater coordination across early care and education sectors, and that can result in administrative efficiencies as well. Additionally, HHS is using both a set of meetings this spring and our large national meeting with State administrators in July to provide training and guidance around the provisions in the new law.

Even with this technical assistance and guidance, we recognize that States need additional new funding to implement reauthorization, which is why the fiscal year 2016 Budget includes a $266 million increase in discretionary funding to help States implement the new law. However, even with these new discretionary resources, funding for child care assistance would fall well short of need, which is why the President's Budget also calls for significant additional mandatory funding for child care.

Access to CCDF-funded child care assistance fell to an all-time low in fiscal year 2013 due to funding constraints, with an average of only 1.4 million children served each month and only a small percentage of children eligible for assistance receive it. To address this serious gap, the President's Budget proposes to invest an additional $82 billion in mandatory funding over the next 10 years to ensure that all low- and moderate-income working families with children under age four have access to high quality, affordable child care.

CDC'S TIPS FROM FORMER SMOKERS CAMPAIGN

Question. This subcommittee has provided significant investments for several years to the Office on Smoking and Health at CDC. This investment in tobacco control has led to reduced rates of smoking, exposure to second hand smoke, and increased smoking cessation. One recent study concluded that tobacco control efforts have prevented 8 million premature deaths in the U.S. since 1964. A critical component of CDC's recent work is the "Tips from Former Smokers" campaign, combined with expanded Quitline support.

What have been the results of the Tips campaign to date, and what are the plans for fiscal year 2016?

Answer. In March 2012, CDC launched the first-ever paid national tobacco education campaign—Tips From Former Smokers (Tips). During the first 3 years of the Tips campaign, ads featured real people living with heart attacks, amputations, and other serious health conditions. Their stories sent a powerful message: Quit smoking now—or better yet, don't start. These hard-hitting ads delivered resulted in an estimated 1.64 million people attempting to quit smoking. Approximately 100,000 are expected to quit for good. Based upon the number of quit attempts, the 2012 Tips campaign prevented at least 17,000 premature deaths. Tips is a "best buy" in public health, at a cost of $393 per year of life saved. The accepted benchmark for cost effective health programs is below $50,000 per year of life saved.

In March 2015, CDC launched a new round of Tips advertisements featuring macular degeneration and colorectal cancer—two diseases that the 2014 Surgeon General's report found were caused by smoking. Early data show that calls to state tobacco quitlines increased by nearly 70 percent in the first few weeks of the ads running. In fiscal year 2016, CDC plans to continue with the Tips campaign with a new round of ads featuring additional health conditions. CDC anticipates running these ads in the first quarter of 2016.

Question. What effect will the rise in e-cigarette use among youth, documented in a CDC report released last week, have on our tobacco control gains?

Answer. Recent increases in e-cigarette and hookah use, combined with declines in use of more traditional products such as cigarettes and cigars, resulted in no change in overall tobacco use between 2013 and 2014. The report also concludes that because the use of e-cigarettes and hookahs is on the rise among middle and high school students, it is critical that comprehensive tobacco control and prevention strategies for youth focus on all tobacco products, and not just cigarettes. FDA is working to finalize the proposed deeming rule on tobacco products and proposes extending its regulatory authority to cover additional products that meet the definition of a tobacco product, including e-cigarettes and hookah. Once the proposed rule becomes final, FDA will be able to take further action to reduce youth tobacco use and initiation through use its regulatory tools, such as age restrictions and rigorous scientific review of new tobacco products. FDA's regulation of tobacco products will complement other, proven tobacco control strategies to achieve our objective of prevention of all forms of youth tobacco use.

HIV/AIDS PREVENTION

Question. For several years, CDC has been emphasizing HIV testing to help control the transmission of HIV, as well as to connect people with HIV to treatment. These efforts have resulted in an increase in people with HIV who are aware of their condition from 75 percent in 2001 to 86 percent a decade later. Yet the rate of new infections has remained stable in recent years, at about 50,000 new HIV infections per year. And some groups are affected more than others. Among races and ethnicities, African Americans continue to be disproportionately affected. So much more remains to be done to prevent HIV transmission. What factors are impeding our efforts to reduce the number of new cases below 50,000 each year? What more can we do to bring down the number of new cases?

Answer. As the number of people living with HIV increases due to better, life-prolonging treatments, so do opportunities for HIV transmission. The number of new infections has remained stable even as the number of persons living with HIV has increased. CDC estimates that that there are only four transmissions per year for every 100 people living with HIV in the United States, an 89 percent decline since the mid-1980s; there was a 9 percent decrease between 2006 and 2010 alone. This achievement reflects the combined impact of investments in testing, prevention, and treatment.

To continue efforts to reduce the number of new cases and achieve the national prevention goals of the National HIV/AIDS Strategy, we must continue working towards: improving the utilization of effective primary prevention tools designed to prevent HIV infection, including pre-exposure prophylaxis; diagnosing people with HIV early; linking newly-diagnosed people as soon as possible to HIV medical care; supporting HIV prevention partners to ensure patients receive ongoing HIV medical care and achieve viral suppression; gaining a better understanding of factors that drive health disparities; and ensuring that young people have the knowledge and skills to avoid infection and establish healthy behaviors for a lifetime.

To further decrease the number of new cases, the fiscal year 2016 Budget proposes to expand existing CDC research and surveillance efforts within the $6 million increase requested for HIV activities to better understanding the characteristics of

persons at risk of transmitting HIV. This year, CDC released first-ever estimates of transmission at each stage of the HIV care continuum that showed:

—Nine in 10 new HIV infections come from people not receiving care.

—People who were successfully keeping the virus under control were 94 percent less likely than those who did not know they were infected to transmit HIV.

These data support CDC's efforts to prioritize funding for prevention services for persons living with HIV, including linkage to care, retention and re-engagement in care, and adherence to HIV treatments to achieve the ultimate goal of viral suppression, and in turn, fewer new HIV cases.

To prevent acquisition of HIV, CDC is also investing in primary prevention efforts, including biomedical and behavioral risk reduction interventions, for persons at highest risk. These efforts—some of which would be funded with the increase requested in the fiscal year 2016 Budget for HIV activities —include implementation of pre-exposure prophylaxis (e.g., planning, educational materials, risk reduction counseling, evaluation, and staffing). With pre-exposure prophylaxis, a person who does not have HIV takes medicine to prevent acquiring HIV. When used consistently, pre-exposure prophylaxis has been shown to greatly reduce acquisition of HIV infection in people who are at substantial risk. In 2014, CDC released clinical guidelines recommending pre-exposure prophylaxis. If targeted to the right populations (e.g., couples where one person is HIV-positive and one is HIV-negative) and used in the right way, pre-exposure prophylaxis has the potential to alter the course of HIV in the United States.

Young people aged 13—24 accounted for a disproportionate percentage of all new HIV infections in the United States (26 percent in 2010), and adolescents report inconsistent use of condoms and may not seek health services because of unique barriers that particularly hinder use of sexual health services. The fiscal year 2016 Budget requests an additional $6 million above the fiscal year 2015 Enacted level to evaluate and improve school HIV prevention activities and increase outreach strategies and interventions for youth at disproportionate risk for HIV infection, including adolescent men who have sex with men.

FISCAL YEAR 2016 BUDGET REQUEST FOR CMS PROGRAM MANAGEMENT

Question. The President's budget maintains investments in CMS to help families get affordable healthcare through the ACA Health Insurance Marketplace. The CMS appropriation is also the primary account that operates the Medicare program, helping seniors get the care they need. Both the growing Medicare population and the important initiatives to encourage high-quality care are significant undertakings for the agency, which is why the budget proposes additional resources to support the increasing workload. Of the $4.3 billion requested for CMS, what proportion of the budget supports Medicare Operations and what are some of these critical functions? Significant growth in the long term care industry has not been matched with increased funding to support CMS' oversight activities that protect seniors. What will be the impact if the Survey and Certification program does not get additional funding this year?

Answer. The fiscal year 2016 CMS Program Management request is $4.2 billion, an increase of $270 million above fiscal year 2015. This request will enable CMS to enhance and continue to effectively administer Medicare, Medicaid, and the Children's Health Insurance Program, as well as health insurance reforms contained in the Affordable Care Act. Of this amount, CMS is requesting $3 billion for Program Operations, an increase of $200 million above the fiscal year 2015 level. Approximately 30 percent, or $899 million, of the Program Operations request supports ongoing contractor operations such as Medicare claims processing. For fiscal year 2016, the Budget requests $784 million for CMS Federal Administrative costs, $51 million above the fiscal year 2015 enacted level. Of this total, $686 million will support a full-time equivalent (FTE) level of 4,671, an increase of 201 FTEs over fiscal year 2015. This staffing increase will enable CMS to address the needs of a growing Medicare population, as well as oversee expanded responsibilities resulting from the Affordable Care Act and other legislation passed in recent years.

The fiscal year 2016 Survey and Certification request is $437 million, a $40 million increase over fiscal year 2015. The increased funding level supports survey frequency levels in response to increasing numbers of participating facilities and improved quality and safety standards. This increase also provides targeted funding for the most serious quality of care concerns by increasing nursing home special focus facility work and enhancing quality monitoring and oversight in the States, territories, islands, and IHS facilities within tribal nations. CMS expects States to complete over 25,000 initial surveys and re-certifications and over 52,000 visits in response to complaints in fiscal year 2016. The Improving Medicare Post-Acute Care

Transformation Act of 2014 increases hospice survey frequencies to no less than once every 3 years. Approximately 87 percent of the request will go to State survey agencies. Surveys include mandated Federal inspections of long-term care facilities (i.e., nursing homes) and home health agencies, as well as Federal inspections of other key facilities. All facilities participating in the Medicare and Medicaid programs must undergo inspection when entering the program and on a regular basis thereafter. In addition, CMS is currently engaged in an effectiveness and efficiency strategy aimed at quality improvement while identifying risk-based approaches to surveying.

TEENAGE USE OF LONG-ACTING REVERSIBLE CONTRACEPTION

Question. Though teen pregnancy rates continue to decline, it is troubling that roughly 1 million teenage girls still become pregnant every year. The United States experiences much higher rates than many other developed nations. In fact, the rate of teen pregnancy in the U.S. is twice as high as in England and nine times as high as Japan and the Netherlands. According to a recent CDC report, nearly 90 percent of teens used birth control the last time they had sex. Unfortunately, very few teens are using the most effective forms of birth control, IUDs and implants, which are known as Long-Acting Reversible Contraception (LARC). What are the major barriers that prevent teens from using LARCs at higher rates? How is HHS working to increase awareness, access, and availability of these types of contraception among teens?

Answer. Research has identified numerous barriers to adolescents' use of LARC (see citations below). Barriers include the fact that many teens know very little about LARC, and that some teens mistakenly think they cannot use IUDs because of their age. Clinics report many barriers to providing LARC to teens, including high upfront costs for supplies, lack of awareness among providers about the safety and effectiveness of LARC for teens, providers lack training on insertion and removal of LARC, and/or providers lack training on a client-centered counseling approach that includes discussing the most effective contraceptive methods first.

HHS is taking several steps to remove these barriers to LARC, among teens and all women of reproductive age:

—The Affordable Care Act removed many cost barriers to LARC when it provided for inclusion in most health coverage of certain women's preventive services without co-pay or deductibles. As identified in comprehensive guidelines supported by the Health Resources and Services Administration, these preventive services required to be covered without cost sharing include contraceptive services for women with reproductive capacity.

—HHS supports the provision of confidential, low cost contraception—including LARC—through the Title X program. Since 1970, the Title X program has provided cost-effective and confidential family planning and related preventive health services for low-income women and men. Title X funded centers serve approximately 4.7 million clients, including one million teens each year (about 20 percent of clients are teens). The program requires funded centers to encourage parent-child communication, counsel minors about sexual coercion, and observe all relevant State laws and any legal obligations, such as notification or reporting of child abuse, child molestation, sexual abuse, rape or incest, as well as human trafficking.

—In 2014, the HHS Office of Population Affairs (OPA), which administers the Title X program, partnered with the Centers for Disease Control and Prevention (CDC) to publish national guidelines about how to provide quality family planning services, which clarify LARC is safe and effective for teens and describe how to meet the unique needs of adolescent clients. The guidelines also recommend counseling procedures that ensure contraception is offered in a client-centered way. Numerous efforts are being taken to increase awareness of these clinical guidelines to all providers of primary care.

—The Title X program funds five national training centers to ensure that Title X providers (and others) have the skills and knowledge needed to implement the guidelines for family planning services. This effort includes training focused on counseling about LARC, LARC insertion, and contraceptive counseling among teens. More information about training resources can be found at www.fpntc.org.

—The Center for Medicaid and Children's Health Insurance Program (CHIP) Services' (CMCS) Maternal and Infant Health Program includes teens in its efforts to improve maternal and infant health. Preventing unintended pregnancy is one of two key strategies of this initiative. Several approaches to removing barriers to LARC are being considered, including reimbursement rates, expand-

ing coverage for services such as immediate postpartum insertion of LARC, removing barriers to same-day provision of LARC such as prior authorization, and discouraging medical management techniques such as requiring clients to "fail" on another method before approving LARC. For more information, see: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Quality-of-Care/Maternal-and-Infant-Health-Care-Quality.html.

—OPA is also taking steps to develop/validate clinical performance measures for contraceptive services, which can be used in the context of quality improvement efforts to improve the quality of contraceptive care that is provided. One of the measures focuses on the percentage of adolescent women at risk of unintended pregnancy that use LARC. While still under development, OPA expects to submit these measures to the National Quality Forum for endorsement this summer, and several Federal programs that address teen pregnancy prevention have already started using this measure on a developmental basis (i.e., Title X, the Center for Medicaid and CHIP Services' Maternal and Infant Health Program, and HRSA's Collaborative Improvement and Innovation Network (CoIIN) to Reduce Infant Mortality).

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OLDER AMERICANS ACT PROGRAMS

Question. Over the next 20 years, nearly 80 million baby boomers will reach retirement age and older Americans will comprise roughly 20 percent of our population. It is unacceptable that Federal investments for critical programs that help older adults live safely at home and eat nutritiously have fallen significantly behind inflation and the increasing population. These programs, like Meals on Wheels, not only allow seniors to remain in their homes, but help avoid high medical and long term care costs that significantly impact Medicaid and Medicare. How will seniors in need of nutrition and supportive services be impacted if the budget for these Older Americans Act programs remains stagnate next year?

Answer. ACL Nutrition Services programs, as well as ACL Home and Community-Based Supportive Services programs, help elderly Americans live at home for longer, delaying the need for much more expensive institutional services.

ACL has requested $40 million in increased funding for Nutrition Services and $38 million in increased funding for Home and Community-Based Supportive Services in fiscal year 2016 to counteract the negative impact on service levels of rising food, labor, and fuel costs.

With regard to Nutrition Services, the Budget—in combination with State and local funding— will support approximately 208 million home-delivered and congregate meals to more than 2.3 million elderly Americans in fiscal year 2016, which will allow ACL to maintain approximately the same level of meals as is currently projected for fiscal year 2015, halting the decline in service levels for the first time since 2009–2010, when these programs received a one-time funding increase from the American Recovery and Reinvestment Act. If fiscal year 2016 funding for ACL Nutrition Services is ultimately held flat with fiscal year 2015 funding levels, however, millions of fewer meals may be served as a result.

With regard to Home and Community-Based Supportive Services, the Budget—in combination with State and local funding—will support increases for a variety of services levels, including those for transportation services; personal care, homemaker, and chore services; and adult day care services. If fiscal year 2016 funding for Home and Community-Based Supportive Services is ultimately held flat with fiscal year 2015 funding levels, an estimated 500,000 fewer rides to doctors and grocery stores, 200,000 fewer hours of assistance to seniors unable to perform activities of daily living, and 100,000 fewer hours of care for dependent adults in supervised, protective group settings may ultimately be provided as a result.

Without the additional resources requested in the Budget, more older adults will be at risk of no longer being able to live at home.

QUESTION SUBMITTED BY SENATOR JACK REED

CDC'S HEALTHY HOMES AND LEAD POISONING PREVENTION PROGRAM

Question. I have been advocating for the full restoration of CDC's healthy homes/lead poisoning prevention program. Addressing environmental causes of health can lead to improved health outcomes and major cost savings. Lead poisoning, for example, costs society $50 billion annually in healthcare, education, and other costs. We have the know-how to prevent lead poisoning and I am pleased that Congress restored some of the funding for this program in fiscal years 2014 and 2015.

Can you tell us what your plans are for the program this year and what you would do with additional resources?

Answer. Lead poisoning poses a health, social, and economic burden for families, communities, and the country. CDC's Healthy Homes and Lead Poisoning Prevention Program protects children from lead exposure and provides national expertise, guidance, and surveillance of childhood lead poisoning in the United States. The fiscal year 2016 Budget includes $16 million for this program and will build on past success in reducing children's blood lead levels in the United States.

In fiscal year 2016, CDC will fund 35 State and local lead poisoning prevention programs to implement proven primary prevention interventions that protect children who live in the highest-risk housing. Examples of these interventions include: housing rehabilitation, housing and health code enforcement, early childhood programs, and publishing guidelines to help healthcare providers identify and manage children with elevated blood lead levels. These interventions are based on CDC-funded data collection, and protect children who live in the highest-risk housing in buildings, blocks, and neighborhoods.

QUESTIONS SUBMITTED BY SENATOR JEANNE SHAHEEN

PREVENTION OF OPIOID MISUSE

Question. Prescription drug abuse is a serious public health problem in New Hampshire, and across the country. And we know that certain prescription drugs can lead to a variety of adverse health effects, including addiction. In New Hampshire, we are seeing the impact of addiction problems. I was pleased to see that your budget includes investments on prescription drug abuse and overdose prevention. I have introduced a bi-partisan, bi-cameral bill to reauthorize the National All Schedules Prescription Electronic Reporting Act which would improve prescription drug monitoring programs across the country.

What role to do see prescription drug monitoring programs playing in addressing the prescription drug abuse, and what more is the administration doing to help educate healthcare providers about appropriate narcotic prescription drug dispensement?

Answer. Prescription drug monitoring programs play an important role in combatting prescription drug abuse. The Department recently launched a targeted initiative aimed at reducing prescription opioid and heroin related overdose, death and dependence. The Department's fiscal year 2016 Budget provides $131 million, an increase of $99 million above fiscal year 2015, to address this critical issue. The Budget includes $65 million, an increase of $45 million above fiscal year 2015, proposed in CDC to expand the Prescription Drug Overdose Prevention for States program to fund all 50 States and Washington, D.C. for a truly comprehensive response to the national epidemic. This funding will provide grants to help implement tailored, State-based prevention strategies such as maximizing the use of prescription drug monitoring programs, enhancing public insurer mechanisms to prevent overdoses, and evaluating their own policies and programs aimed at addressing the epidemic. This will be accomplished in part by promoting best practices in PDMPs among State grantees. For example, proposed systems improvements include:

—Interstate prescription drug monitoring program interoperability;
—Improved proactive reporting and links to other systems such as Medicaid; and
—National patient safety improvements and improvements in data quality and monitoring, with an emphasis on real-time mortality data.

Also within this initiative, CDC will lead the development of new opioid prescribing guidelines for non-cancer chronic pain which will help prescribers know how and when to safely and appropriately prescribe opioids. CDC and SAMHSA will

improve State prevention programs by helping States understand how to use prescription drug monitoring programs, strategic planning, and other existing data systems in prevention planning, and ONC will fund challenge awards to innovate the design and use of health information technology products to access prescription drug monitoring programs in live clinical applications.

DIABETES PREVENTION, RESEARCH AND CARE

Question. I am concerned that we are missing the mark in translating the incredible diabetes research being done across the Federal Government into clinical care initiatives for healthcare providers use. Senator Collins and I have legislation to create a Diabetes Clinical Care Commission that would bring together experts in diabetes care, patients, and the agencies in the Federal Government that work on diabetes to work together on these issues of better clinical care for people with pre-diabetes, diabetes and the diseases that are complications of diabetes. I welcome your comments on such a commission, as well as what steps this budget takes to address the diabetes epidemic, which has such a huge humanitarian and financial toll on patients and the healthcare system.

Answer. Diabetes research, prevention, and care are an important priority for the Department. About 29 million Americans have diabetes, and over 200,000 die each year of related complications. To foster collaboration among various Federal agencies addressing diabetes, the Diabetes Mellitus Interagency Coordinating Committee (DMICC) was established to ensure coordination across Federal efforts to prevent and treat diabetes. There are over thirty Federal agencies who are members in the DMICC. The missions of these agencies and approaches to the diabetes epidemic are complementary and informed by stakeholder input linking basic research; investigating the cause of diabetes and identifying targets for therapy; clinical trials; translation of new knowledge into clinical practice and health decisionmaking; delivery of healthcare services and public health interventions; and optimizing healthcare access, delivery and public health measures. The DMICC is one vehicle through which agencies within the Department of Health and Human Services provide leadership and coordination between government agencies in order to avoid duplication of efforts and to maximize scarce resources. The DMICC currently carries out the activities proposed under the National Diabetes Clinical Care Commission, but I would be happy to work with you on ways in which the DMICC's work could be further strengthened.

The Budget request builds on recent progress made to address diabetes by including $10.9 billion in funding across the Department for diabetes care and related research, an increase of $1.1 billion over fiscal year 2015. Highlights of these investments include:

—The fiscal year 2016 Budget proposes a 3-year extension of the Special Diabetes Program for Type 1 Diabetes and for Indians (through fiscal year 2018), at $150 million per year for each of the two programs. These programs support research at the National Institutes of Health and implementation of proven interventions in Indian Country. The recently-enacted SGR law (Medicare Access and CHIP Reauthorization Act of 2015, Public Law 114–10) extended funding for these important programs through fiscal year 2017.

—The Budget continues support for CDC's National Diabetes Prevention Program with an investment of $10 million, the same as fiscal year 2015. The National Diabetes Prevention Program is an evidence-based lifestyle intervention program for preventing type 2 diabetes that teaches participants strategies for incorporating physical activity into daily life and eating healthy. NIH studies have shown that lifestyle changes, such as diet and physical activity, can lower the risk of developing type 2 diabetes by over 50 percent in adults at high risk for the disease.

—HRSA's Health Centers Program is making strides in diabetes care and control for adult patients. The Budget's proposal to expand the capacity of health centers will help drive greater strides in diabetes care and control for adult patients. The recently-enacted SGR law extends funding for these health centers. In 2013, 69 percent of health center patients with diabetes had their diabetes under control, exceeding the Medicaid HMO average of 55 percent. For example, in New Hampshire, about 83 percent of diabetic health center patients have their diabetes under control.

LOW INCOME HOME ENERGY ASSISTANCE PROGRAM (LIHEAP)

Question. As you know, the Low Income Home Energy Assistance Program (LIHEAP) is the main Federal program to help low-income households and seniors

with their energy bills, providing vital assistance during both the winter and summer months.

I understand that HHS held back roughly $34 million in LIHEAP funding from fiscal year 2015. If true, will those be distributed to States soon? The funds could particularly help States like New Hampshire that are recovering from the tough winter we experienced this year.

Answer. LIHEAP is a lifeline for many vulnerable Americans who often have to make tough choices within their household budgets. We expect that remaining LIHEAP funds will be distributed to States before the end of the third quarter of fiscal year 2015.

Question. In this budget request, you are asking for $200 million to go toward a LIHEAP innovation program. I am concerned that this may take funds away from the core function of the program at a time when many households who are eligible for the program are not receiving funds. I am also concerned about the use of fuel switching in the innovation program. If you do move forward with this program, what steps will you take to ensure that it would be implemented in a way that my oil-heat constituent can still maximize their access to the program?

Answer. The Utility Innovation Fund will support efforts to better reduce low-income households' utility bills over the long-term. ACF will provide $200 million in competitive grants to current LIHEAP grantees to encourage partnerships with utilities and community-based organizations to test innovative strategies to reduce the home energy burden of the highest burden low income households. For example, the competitive funds may support efforts to test strategies related to reducing energy burden, supporting more efficient and clean energy sources, and improving households' ability to pay utility costs. Each grantee will be required to conduct a rigorous evaluation to develop lessons learned and, to the extent possible, assess the efficacy of interventions. HHS does not prioritize specific fuel types nor is it our intent to designate a preferred fuel type. Instead grantees would assess the home's energy use and recommend cost-effective measures to make that home more energy efficient.

QUESTIONS SUBMITTED BY SENATOR BRAIN SCHATZ

TELEHEALTH SERVICES AND REIMBURSEMENT

Question. My understanding is that the CMS Innovation Center can waive Medicare restrictions on telehealth for various initiatives and experiments. For example, in the Next Generation ACO program, CMS waived the 1834(m) restrictions on geographic location and where the patient can be located during telehealth visits. However, CMS did not lift the restrictions on store-and-forward technologies, on provision of telehealth services by occupational and speech therapists, and more. Can you please tell me why not, and what more is being done to expand telehealth initiatives from the perspective of the Innovation Center?

Answer. The telehealth waiver in the Next Generation ACO Model addressed the originating site requirement, which was the barrier most often cited by commenters in response to CMS' Request for Information on this payment policy. CMS remains open to exploring waivers of additional elements of payment for telehealth services in later years of the Next Generation Model and/or in other Innovation Center models, and will consult with the Office of the National Coordinator for Health Information Technology in these policy discussions.

Question. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, or BIPA, in Section 223, required HHS to conduct a study to identify several important topics within telehealth services and reimbursement. The law required that a report be submitted to Congress no later than 2 years after it was passed, but to our knowledge no report has been issued. Can we count on CMS to submit this report by January 19, 2017, before a new Administration begins?

Answer. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, or BIPA, requires HHS to study whether there are additional practitioners, settings or sites, or geographic areas that should be included under the telehealth benefit. The Centers for Medicare & Medicaid Services (CMS) has addressed this requirement through changes in law or regulations resulting in the addition of practitioners, settings, sites, and geographic areas to the telehealth benefit. For instance, Congress added telehealth originating sites through Section 149 of MIPPA 2008, which added Skilled Nursing Facilities, End Stage Renal Disease facilities, and Community Mental Health Centers. Medicare has continued to grow the telehealth program since its inception in 2004. There are now 75 services that can be furnished via telehealth. Since 2004, CMS has added numerous services to the

list including preventive services, transitional care management, and new psychiatric services. In CY 2012, CMS also broadened our criteria for adding new services to the list. Effective July 5, 2011, CMS implemented rules to permit hospitals and Critical Access Hospitals (CAHs) to provide telemedicine services to their patients through written agreements with a distant-site hospital or a distant-site telemedicine entity. Further, CMS streamlined credentialing and privileging for telemedicine physicians and practitioners in CAHs, and effective in CY 2014, CMS modified our regulations regarding originating sites to define rural Health Professional Shortage Areas as those located in rural census tracts as determined by the Office of Rural Health Policy. Adopting the more precise definition of "rural" for this purpose expanded access to healthcare services for Medicare beneficiaries located in rural areas. Finally, in CY 2014, CMS revised our policy to so that geographic eligibility for an originating site would be established and maintained on an annual basis, consistent with other telehealth payment policies. We are happy to work with Congress on exploring additional practitioners and geographic areas that may be appropriate for inclusion under the telehealth benefit.

Question. While Medicare has abundant regulations on telehealth reimbursement, Medicaid does not. As such, States have been able to experiment with multiple payment and incentive schemes in telehealth. What has CMS learned from the vast experience on the Medicaid side with telehealth that could apply to Medicare?

Answer. Telemedicine is an important part of the healthcare delivery system and can improve access to care for all patients, particularly those rural or underserved populations. CMS is working across its programs to ensure access to high quality care through a variety of tools, including telemedicine.

The Medicare program provides telehealth services for Medicare beneficiaries for a limited number of Part B (outpatient) services furnished through a telecommunications system by a physician or practitioner to an eligible telehealth individual, where the physician or practitioner providing the service is not at the same location as the beneficiary. The Medicare Shared Savings Program statute encourages accountable care organizations (ACOs) to coordinate care through the use of telehealth, remote patient monitoring, and other such enabling technologies. ACOs participating in the Shared Savings Program and the Pioneer ACO Model are encouraged to use these technologies.

In Medicaid, States are encouraged to use the flexibility in the program law to create innovative payment methodologies for services that incorporate telemedicine technology.

While the current Federal Medicaid statute does not recognize telemedicine as a distinct service, States have the option/flexibility to determine whether (or not) to cover telemedicine; what types of telemedicine to cover; where in the State it can be covered; how it is provided/covered; what types of telemedicine practitioners/providers may be covered/reimbursed, as long as such practitioners/providers are "recognized" and qualified according to Medicaid statute/regulation; and how much to reimburse for telemedicine services, as long as such payments do not exceed Federal Upper Limits.

To further facilitate the use of telemedicine, States are not required to submit a (separate) SPA for coverage or reimbursement of telemedicine services, if they decide to reimburse for telemedicine services the same way/amount that they pay for face-to-face services/visits/consultations.

CMS will continue to work across our programs and in collaboration with the Office of the National Coordinator for Health Information Technology to utilize technological advances, such as telemedicine to ensure all Americans have access to high-quality healthcare.

Question. Hawaii faces significant issues with the impact of immigrants from the Compact of Free Association (COFA) States. Telehealth may be a mechanism to mitigate this impact by allowing potential immigrants to stay in their own countries. Has CMS examined the use of telehealth to mitigate the Compact impact?

Answer. In limited circumstances, Federal law extends Medicaid eligibility to certain citizens of nations that have a Compact of Free Association (COFA) with the United States at a state's option. As you know, Hawaii has taken up that option and extends Medicaid benefits to lawfully residing children and pregnant women. Beyond Medicaid, COFA migrants are eligible to purchase health insurance and receive Federal tax credits and cost-sharing reduction (APTC/CSR) through the state's health insurance exchange, the Hawaii Health Connector.

In Medicaid, States are encouraged to use the flexibility in the program law to create innovative payment methodologies for services that incorporate telemedicine technology and are not required to submit a (separate) State plan amendment (SPA) for coverage or reimbursement of telemedicine services, if they decide to reimburse

for telemedicine services the same way/amount that they pay for face-to-face services/visits/consultations.

Question. In order for telehealth to expand, robust data on utilization and outcomes is needed. What mechanisms are currently underway to track telehealth utilization and outcomes in Medicare and Medicaid, and then to disseminate the findings?

Answer. The Health Care Innovation Awards (HCIA) have several awardees that are using telehealth as part of their intervention. Telehealth is being used in different settings and targeting different acute and chronic conditions. Telehealth activities under Round 1 of HCIA are being evaluated by independent evaluation contractors. Findings to date are mostly qualitative and describe implementation experiences due to the availability of data. For awardees with a telehealth component in their interventions, the contractors will continue to collect telehealth utilization and selected outcome measures to the extent that the data is available. However, the findings will be limited by data availability and the sample size for most of these awardees. The Innovation Center anticipates releasing the next set of evaluation findings for Round 1 of HCIA next year. We look forward to learning about telehealth from future findings about these awards.

In addition to the HCIA awards, the Innovation Center will be evaluating the Next Generation ACO Model, which includes a waiver of telehealth payment rules, yielding descriptive data on utilization of telehealth services, and not outcomes. We are happy to work with Congress on exploring additional ways to promote and/or expand telehealth services.

QUESTIONS SUBMITTED BY SENATOR TAMMY BALDWIN

WISCONSIN'S MEDICAID WAIVER

Question. Instead of expanding Wisconsin's Medicaid program, BadgerCare, under the ACA, our Republican Governor kicked almost 63,000 individuals off of their Medicaid coverage and into the ACA's Marketplace. As you know, I worked with CMS to include terms and conditions in Wisconsin's Medicaid waiver that required our Governor and CMS to track the Wisconsinites he kicked off BadgerCare to hold him accountable for those who may not have successfully obtained Marketplace coverage.

Now that the second ACA open enrollment period has closed, when will you have the updated data on the number of Wisconsinites who have successfully made the transition to Marketplace coverage?

Answer. My understanding is that, since the transition, CMS has shared Marketplace enrollment data with the State on two occasions and in between the period of those data matches, a Special Enrollment Period was provided for Wisconsinites who had lost Medicaid coverage and had not transitioned to Marketplace coverage.

CMS in the process of working with the State to provide an additional Marketplace data set and the parameters around the use of that data, though CMS believes that the State has fulfilled its obligations under its 1115 Waiver Transition Plan and that no further data matches are required.

As you note, as a requirement to meet its 1115 Waiver Transition Plan, Wisconsin conducted multiple rounds of outreach to the nearly 63,000 individuals you mention to help provide for a seamless transition to coverage available through the Marketplace. As part of this effort, the State sent several letters to transitioning members that included information about enrolling in Marketplace coverage, conducted multiple rounds of outreach calls encouraging these individuals to apply to the Marketplace, and shared information through its "Regional Enrollment Network."

HHS' RESPONSE TO INDIANA HIV EPIDEMIC

Question. I am alarmed by the recent, tragic situation in Indiana, where there have been 130 cases of HIV identified based on injection drug use in the last 3 months. According to the CDC, the majority of cases were linked to syringe-sharing partners injecting prescription opioids. Not only does this crisis highlight the urgency in addressing the prescription drug abuse epidemic, but the need to increase our efforts to contain HIV, including by expanding efforts to promote the use of clean needles.

I have long supported ending the ban on the use of Federal funds for syringe exchange programs. Numerous studies have shown syringe exchange programs can be an evidence-based and cost-effective means to lower HIV and hepatitis infections, reduce the use of illegal drugs and help connect people to medical treatment, including substance use treatment.

What is the CDC doing to help address the crisis in Indiana and to advance injection safety, particularly for individuals living with HIV?

Answer. The Indiana State Health Department has the lead in the response effort to the HIV outbreak in Scott County, which appears to be driven by intravenous use of opioid prescription painkillers. Several HHS agencies including CDC, HRSA, SAMHSA and FDA, are working closely with Indiana officials and providing assistance.

The Department, and the Administration, is committed to making the dream of an AIDS-free generation a reality through our efforts to better prevent and treat HIV. Because opioid use appears to be the main driver of the current Indiana outbreak, I also want to underscore that combatting opioid abuse is a top priority at the Department of Health and Human Services. We believe that through evidence-informed interventions and bipartisan solutions we can put a stop to opioid drug-related dependence and overdose.

CDC is assisting with the Indiana investigation at the request of State health officials, who are leading the response and have reacted promptly to a severe, rapidly spreading-outbreak. CDC is leading epidemiological and surveillance efforts and is also assisting with HIV testing in the community. CDC currently has several experts in the field. CDC expects to continue to work closely on-the-ground with our colleagues in Indiana for as long as they need assistance. Specific CDC activities include:

—Efforts to diagnose those infected with HIV and link them to needed medical care, including collecting blood samples for the State laboratory to use in testing for hepatitis (B and C), syphilis, and tuberculosis;

—Conducting interviews with those infected with HIV to identify additional contacts who need to be reached with testing and linked to care and treatment, if also infected;

—Laboratory testing of specimens to help determine how recently infections occurred and to identify clusters of infection; and

—Educational efforts to reach healthcare providers and those at risk with education efforts and referrals to prevention services, including pre-exposure prophylaxis, post-exposure prophylaxis, syringe exchange services, and drug treatment programs;

Please also see:

—CDC's Health Advisory: http://emergency.cdc.gov/han/han00377.asp

—Morbidity and Mortality Weekly Report (MMWR): http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6416a4.htm?s cid=mmmm6416a4 w

Question. What are the consequences if Congress continues the ban on the use of Federal funds for syringe exchange?

Answer. As you stated, Federal funding cannot be used for syringe exchange programs due to a Congressional ban. States may use other available sources of funding to support such programs in their States, consistent with State and local law.

Scientific evidence has found that syringe exchange programs can reduce needle sharing among drug users, resulting in positive behavior change that can reduce transmission of HIV and other blood-borne infections. The evidence shows that syringe exchange programs do not result in negative consequences such as increases in injection frequency, in injection drug use, or in unsafe disposal of needles in the community. In fact, syringe exchange programs can provide a positive pathway to prevention for substance abusing persons. Many communities have found syringe exchange programs to be an effective component of their HIV prevention efforts for the injection drug user population.

The Administration supports a consistent policy that would allow Federal funds to be used in locations where local authorities deem syringe exchange programs to be effective and appropriate. This policy is reflected again in the fiscal year 2016 President's Budget. Without Federal support for syringe exchange programs, HHS is not able to leverage all opportunities to reduce HIV and hepatitis C infections, prevent overdose deaths, and link people to drug treatment programs. A recent study from Bramson et al. published on January 15, 2015 in the Journal of Public Health Policy (Vol. 36, 2, 212–230) found that, in the States examined where State and local funding for Syringe Services Programs (SSPs) was provided, estimated HIV incidence remained low over time or decreased. We will continue to work with Congress on this important issue.

NATIONAL BREAST AND CERVICAL CANCER EARLY DETECTION PROGRAM

Question. In 2007, I was the lead author of the National Breast and Cervical Cancer Early Detection Program Reauthorization Act in the House, with my colleague Vice Chairwoman Mikulski in the Senate. I am committed to protecting and enhanc-

ing this critical program so that vulnerable women have access to lifesaving screening services, and so I am extremely frustrated that your Budget—once again—requests significant cuts for this program.

Despite increased access to screenings under the ACA, many women still face significant barriers to obtaining essential cancer screenings and remain eligible under the program, so why does the Administration continue to propose these harmful cuts?

Answer. With the proposed funding level for fiscal year 2016, CDC's cancer screening programs will continue to complement the benefits provided through the Affordable Care Act. CDC will continue to support the provision of direct services to people who are not covered by insurance, but the Budget reflects an expected decrease in the number of women who will be eligible for these cancer screening services due to expanded insurance coverage under the Affordable Care Act. To maximize the impact of the new coverage expansions, the Budget continues the fiscal year 2015 policy to allow, but not require, all States to shift their funds from direct services to population-level interventions (such as outreach and education activities). CDC expects State support of population-level interventions will help improve access to cancer screenings available through the Affordable Care Act and CDC's cancer screening programs.

SUBCOMMITTEE RECESS

Senator BLUNT. The subcommittee stands in recess until 10 a.m. Thursday, April 30.

Thank you, Secretary.

[Whereupon, at 11:57 a.m., Thursday, April 23, the subcommittee was recessed, to reconvene at 10 a.m., Thursday, April 30.]